UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessment for the dimethylurea herbicide diuron. The Agency has revised the human health and environmental effects risk assessments based on the comments received during the public comment period and additional data from the registrant. Based on the Agency's revised risk assessments for diuron, EPA has identified risk mitigation measures that the Agency believes are necessary to address the human health and environmental risks associated with the current use of diuron. EPA is now publishing its reregistration eligibility, and risk management decision. The Agency's decision on the individual chemical diuron can be found in the attached document entitled, "Reregistration Eligibility Decision for Diuron" which was approved on September 30, 2003. A tolerance reassessment was completed in July of 2002. This RED document contains that tolerance reassessment decision as well as the Agency's decisions on the mitigation needed for other human health and environmental risks.

A Notice of Availability for the Reregistration Eligibility Decision for Diuron is being published in the *Federal Register*. To obtain copies of the RED document, please contact the Pesticide Docket, Public Response and Program Resources Branch, Field and External Affairs Division (7506C), Office of Pesticide Programs (OPP), USEPA, Washington, DC 20460, telephone (703) 305-5805. Electronic copies of the RED and all supporting documents are available on the Internet. See www.epa.gov/pesticides/reregistration/status.htm.

As part of the Agency's effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), the Agency is undertaking a special effort to maintain open public dockets and to engage the public in the reregistration and tolerance reassessment processes. During the public comment period, comments on the risk assessment were submitted by Griffin L.L.C., the technical registrant. A close-out conference call with interested stakeholders was conducted on September 29, 2003, to discuss the risk management decisions and resultant changes to the diuron labels.

Risks summarized in this document are those that result only from the use of diuron. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. The Agency did not perform a cumulative risk assessment as part of this reregistration review of diuron because the Agency has not yet determined if there are any other chemical substances that share a common mechanism of toxicity with diuron (see Section 6 of the Human Health Risk Assessment, dated July 9, 2003). For purposes of this risk assessment, EPA has assumed that diuron does not have a common mechanism of toxicity with other substances.

In the future, the registrant may be asked to submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether diuron shares a common mechanism of toxicity with any other substance. If the Agency identifies other substances that share a common mechanism of toxicity with diuron, we will perform aggregate exposure assessments on each chemical, and will begin to conduct a cumulative risk assessment. The Agency has developed a framework for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance was issued on January 14, 2002 (67 FR 2210-2214), and is available from the OPP Website at: http://www.epa.gov/oppfod01/trac/science/cumulative_guidance.pdf.

This RED contains the necessary labeling changes for diuron. Product labels must be revised by the manufacturer to adopt the changes set forth in Section IV of this document. Instructions for registrants on submitting revised labeling and the time frame established to do so can be found in Section V of this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by diuron. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the proposed label changes, please contact the Special Review and Reregistration Division representative, Diane Isbell at (703) 308-8154.

Betty Shackleford, Acting Director
Special Review and
Reregistration Division

Attachment

Reregistration Eligibility Decision

for

Diuron

List A

Case 0046

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Glossary of Terms and Abbreviations

AGDCI	Agricultural Data Call-In
ai	Active Ingredient
aPAD	Acute Population Adjusted Dose
AR	Anticipated Residue
BCF	Bioconcentration Factor
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DWLOC	Drinking Water Level of Comparison.
EC	Emulsifiable Concentrate Formulation
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
G	Granular Formulation
GENEEC	Tier I Surface Water Computer Model
GLN	Guideline Number
HAFT	Highest Average Field Trial
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOD	Limit of Detection
LOAEL	Lowest Observed Adverse Effect Level
MATC	Maximum Acceptable Toxicant Concentration
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Water Quality Assessment
NCFAP	National Center for Food and Agricultural Policy
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level

OP	Organophosphate
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLC	Single Layer Clothing
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
TRED	Tolerance Reassessment Progress and Risk Management Decision
TRR	Total Radioactive Residue
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UF	Uncertainty Factor
UV	Ultraviolet
WPS	Worker Protection Standard

Executive Summary

EPA has completed its review of public comments on the preliminary risk assessments and is issuing its risk management decision for diuron. The revised risk assessments are based on a review of the required target data base supporting the use patterns of currently registered products and additional information received during the public comment periods. After considering the risks identified in the revised risk assessment, EPA developed its risk management decision for uses of diuron that pose risks of concern. Risks from N'-(3-chlorophenyl)-N,N-dimethyl urea (MCPDMU) (water only) 3,4-dichlorophenylurea (DCPU) and 3-(3,4-dichlorophenyl)-1-methylurea (DCPMU), the primary metabolites of diuron, are also considered in the assessment. The decision is discussed fully in this document. A tolerance reassessment was completed in July of 2002. For completeness, the results of the tolerance reassessment are incorporated in this document, including additional information on surface water monitoring.

Diuron is registered for pre- and post-emergent herbicide treatment of both crop and non-crop areas, as a mildewcide and preservative in paints and stains, and as an algaecide in commercial fish production, residential ponds and aquariums. Diuron was first registered in 1967.

Estimates for total annual domestic use average approximately nine to ten million pounds of active ingredient. Approximately two thirds is used on agricultural crops and the remaining one third on non-crop areas. Diuron is used on 33 crops. Crops with the highest percent crop treated are citrus, berries, asparagus and pineapple. In terms of pounds applied, oranges and cotton account for the greatest agricultural use. Right-of-way applications (e.g., the area around railroad tracks) are the greatest non-agricultural use of diuron, with approximately 2 to 3 million pounds applied annually.

Risks summarized in this document are those that result only from the use of diuron. The Food Quality Protection Act (FQPA) requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. The Agency did not perform a cumulative risk assessment as part of this reregistration review of diuron because the Agency has not yet determined if there are any other chemical substances that share a common mechanism of toxicity with diuron (see Section 6 of the Human Health Risk Assessment, dated July 9, 2003). For purposes of this risk assessment, EPA has assumed that diuron does not have a common mechanism of toxicity with other substances.

Dietary Risk - Food

EPA's dietary risk analysis evaluated acute, chronic (non-cancer) and cancer risk for diuron. Anticipated residues from field trial data were used to estimate the dietary exposure to diuron from the diets of the U.S. population as well as certain population subgroups. The field trials were conducted at the highest application rates for the crop tested and therefore, the residues from these trials are considered high end. It should be noted that the U.S. Department of Agriculture's Pesticide Data Program (PDP) monitoring data are available for diuron alone, indicating no detectable residues of the parent compound in citrus, milk and other sampled commodities monitored for diuron. However, these data have not been used in the risk assessment because the PDP program only monitored for diuron, the parent compound, and did not monitor for the metabolites.

The Agency has not performed an acute dietary risk assessment of diuron because no adverse effects attributed to a single exposure were identified in any available study. The chronic non-cancer dietary analysis indicates all risk estimates are below EPA's level of concern for all population subgroups. The chronic dietary risk estimate for food is about 3% of the chronic PAD for the U.S. population and about 7% of the chronic PAD, for the highest exposed population subgroup, children (1-6 years). The estimated cancer dietary risk associated with the use of diuron shows a lifetime risk estimate of 1.68×10^{-6} for the general population. However, the Agency does not believe potential dietary cancer risk to be of concern because the residues used in the calculations are from field trials conducted at the highest application rates and some processing data are still outstanding. Therefore, the exposure calculation is a conservative estimate.

Dietary Risk - Drinking Water

Drinking water exposure to pesticides can occur through groundwater and surface water contamination. For chronic risk from diuron, drinking water monitoring data from South Florida Water Management District and the California Department of Pesticide Regulation were used in addition to USGS NAWQA data from the South Florida, Georgia-Florida Coastal Plain and Apalachicola-Chattahoochee-Flint River were used to determine the estimated environmental concentrations (EECs) in surface water. Estimated drinking water concentrations for ground water are based on the SCI-GROW model, which is a Tier I assessment that provides a conservative estimate. The modeled estimates indicate that ground water concentrations of diuron and its metabolites are not of concern.

The estimated environmental concentrations (EECs) for surface water from monitoring data (<1 ppb) do not exceed the drinking water level of comparison (DWLOC) of 28 ppb and are not of concern for the general population or any sub-group.

For diuron potential cancer risk, EPA has considered average values from monitoring data ranging from 0.16 to 0.28 ppb, yielding risk estimates in the 1×10^{-6} range.

For the degradate MCPDMU, the EEC for surface water has been estimated to be <1ppb, using monitoring data. The drinking water assessment for MCPDMU can be further refined with additional environmental fate data. These data are required.

Residential Risk

There are two potential sources of exposure to diuron in a residential setting - as an algaecide in ponds and aquariums, and as a preservative or a mildewcide in paints. Exposure from the dermal and inhalation routes are combined for each residential use.

The algaecide products are formulated as tablets/blocks and as a liquid. There are no exposure data for the use of the algaecide tablets/blocks. Since the products are formulated as tablets/blocks and dissolve in less than 5 minutes, minimal exposure is expected and was not quantified. The liquid is used at a rate of one teaspoon (5 ml) for every 10 gallons of aquarium or pond water, once a month or when algae growth reappears. Residential exposure may result from measuring the liquid and pouring the liquid into the aquarium or pond. Exposure is expected to be short-term (1 to 30 days). These risks are not of concern.

Residential painters using paints and stains were assumed to use airless sprayers and paint brushes. Exposure is expected to be short-term (1 to 30 days). For homeowners, the airless sprayer is assumed to be used for outdoor applications only. For indoor applications, EPA assumed that painting would be restricted to small rooms such as bathrooms (high potential for moisture) where an airless sprayer is unlikely to be used. These risks are not of concern.

There are no residential uses that would result in chronic exposure to diuron. Because less than 1 percent of all paint contains diuron, cancer risk from residential use is expected to be negligible.

Diuron Aggregate Risk

An aggregate risk assessment looks at the combined risk from dietary exposure (food and drinking water pathways) as well as exposures from non-occupational sources (e.g., residential uses).

Acute Aggregate Risk. There are no adverse effects expected from a single exposure to diuron; therefore, an acute risk assessment was not conducted.

Short-term Aggregate Risk. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water. Short-term aggregate risks from food, residential inhalation, and drinking water are not of concern.

Chronic (Non-cancer) Aggregate Risk. The chronic (non-cancer) aggregate risk assessment addresses exposure to diuron residues in food and water; there are no diuron uses that could result in chronic residential exposure. Monitoring data from the South Florida Water

Management District and the California Department of Pesticide Regulation were used in addition to USGS NAWQA data from the South Florida, Georgia-Florida Coastal Plain and Apalachicola-Chattahoochee-Flint River. The estimated environmental concentration (EEC) for surface water (<1 ppb) does not exceed the drinking water level of comparison (DWLOC) of 28 ppb for the most sensitive population subgroup (children 1-6). Therefore, the chronic non-cancer DWLOCs are greater than the surface water EECs indicating that chronic dietary (food + water) risks are below EPA's level of concern. Chronic aggregate risk is also below EPA's level of concern.

Chronic (Cancer) Aggregate Risk. Dietary risk from food is estimated at 1.68×10^{-6} based on field trial data and assuming maximum application rates. This estimate can be refined with additional residue data. Based on monitoring data, drinking water cancer risk is estimated in the 1×10^{-6} range. Exposure from residential uses is negligible. Although the combined risk exceeds 1×10^{-6}, EPA believes that, given the weight of evidence, diuron cancer risk is not of concern. The Agency does not apply the negative risk standard for cancer (1×10^{-6} or one in a million) as a bright line test because of the lack of precision in the quantitative cancer risk assessment. There are protective assumptions in both the toxicological data used to derive the cancer potency of a substance and in the exposure calculations.

MCPDMU Aggregate Risk

As discussed above (under Drinking Water Dietary Risk), diuron degrades in water to MCPDMU. Because no toxicology data are available for MCPDMU, the Agency used data from a structurally similar compound, monuron, to assess the potential cancer risk from MCPDMU. Based on the algaecidal use in commercial fish ponds, the dietary cancer risk from catfish alone is 1.02×10^{-7} and is not of concern.

Monitoring data, adjusted to account for all potential metabolites, indicate that environmental concentrations of MCPDMU would be <1 ppb, which is less than the calculated DWLOC of 2 ppb. Thus, the aggregate risk of MCPDMU is not of concern.

Occupational Risk

The Agency has identified 31 handler scenarios resulting from mixing/loading and applying diuron for crop and non-crop uses. Of the 31 scenarios, all short- and intermediate-term exposures resulted in a Margin of Exposure (MOE) at or near the target of 100 with personal protective equipment (PPE) and engineering controls (e.g., closed mixing and loading systems), as appropriate.

For the occupational paint assessment, painters using an airless sprayer (MOE = 56) is of concern (with PPE).

For the cancer assessment, the following scenarios are potentially of concern (with PPE): applying with a right-of-way sprayer (risk = 1.3e-4); applying in an industrial/commercial setting

with a high-pressure handwand (risk = 2.4e-4); mixing/loading/applying wettable powder products with a low-pressure handwand (risk = 1.5e-4); loading and applying with a gravity feed backpack spreader (risk = 1.6e-4); and loading and applying with a belly grinder (risk = 3.1e-4).

Ecological Risk

Diuron is persistent and is stable to hydrolysis. Calculated half-lives in aqueous and soil photolysis are 43 and 173 days, respectively. Half lives in laboratory aerobic and anaerobic soil metabolism studies are 372 and 1000 days, respectively. However, in a viable laboratory aquatic system, degradation occurred with half-lives of 33 and 5 days in aerobic and anaerobic systems, respectively. In soil, the half lives of diuron and its degradate DCPMU range from 73 to 139 days and 217 to 1733 days, respectively.

Most of the RQ values are 9 or below, including birds (acute), mammals, freshwater fish, estuarine fish, freshwater invertebrates, and estuarine invertebrates. The highest RQ value for non-target aquatic plants from railroad/right-of-way treatment at the maximum application rate is 172. The RQs for non-target terrestrial plants range from 1 to 77 for acute risk.

Endangered Species

EPA has completed an "Effects Determination" for endangered and threatened salmon and steelhead species and the potential for indirect effects on these fish from damage to their aquatic plant cover in water bodies in California and the Pacific Northwest.

The Agency has concluded that agricultural crop uses of diuron will have no effect on Pacific salmon and steelhead except at certain high use rates, on walnuts, filberts, and peaches, and that non-crop uses may affect 25 salmon and steelhead evolutionarily significant units (ESUs). For those ESUs that may be affected by diuron use, EPA will consult with the National Marine Fisheries Service to determine what protective measures are needed. The protective measures are communicated to the public in county-specific bulletins. Other species and geographic areas have not yet been evaluated. For additional information, please see the document titled, "Diuron, Analysis of Risks to Endangered and Threatened Salmon and Steelhead," dated July 30, 2003. See http://www.epa.gov/oppfead1/endanger/effects/diuron_analysis_final2.pdf.

Risk Mitigation Summary

To mitigate risks of concern posed by the use of diuron, EPA considered the mitigation proposed by the technical registrant, as well as risk mitigation ideas from other interested parties, and has decided on a number of label amendments to address the worker, residential and ecological concerns. A summary of the risk mitigation is listed below. A complete discussion of the risk assessments, and the necessary label amendments to mitigate risks posed by the use of diuron, are presented in Chapter IV of this RED.

- All wettable powder products will be voluntarily canceled.
- Reduction in application rate and increased treatment intervals, and limit the number of applications for some crops.
- Use of the backpack sprayer is prohibited.
- Implement use of PPE and engineering controls for some workers.
- Eliminate aerial applications except for rights-of-way, alfalfa, cotton, winter barley, winter wheat, sugarcane, and grass seed crops.
- Best management practices to reduce spray drift.

Conclusions

The Agency is issuing this Reregistration Eligibility Document (RED) for diuron, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for complying with any required label changes for products containing diuron. With the addition of the label restrictions and amendments detailed in this document, the Agency has determined that all currently registered uses of diuron are eligible for reregistration.

The risk assessments for diuron are based on the best scientific data currently available to the Agency and are adequate for regulatory decision making.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (referred to as EPA or "the Agency"). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide, to determine the need for additional data on health and environmental effects, and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment during reregistration. It also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. The FQPA also amends the FFDCA to require a safety finding in tolerance reassessment based on factors including an assessment of cumulative effects of chemicals with a common mechanism of toxicity.

Diuron is used as a pre- and post-emergent herbicide treatment on a variety of both crop and non-crop areas. It is also used as a mildewcide in paints and stains, and as an algaecide in commercial fish production. At this time, the Agency does not have data available to determine with certainty whether diuron has a common mechanism of toxicity with other pesticides. Therefore, for the purposes of this risk assessment, the Agency has assumed that diuron does not share a common mechanism of toxicity with other pesticides. If the Agency identifies other substances that share a common mechanism of toxicity with diuron, EPA will consider whether a cumulative assessment is warranted. The Agency has developed a framework for conducting cumulative risk assessments on substances that have a common mechanism of toxicity. This guidance was issued on January 16, 2002 (67 FR 2210-2214), and is available from the OPP Website at: http://www.epa.gov/oppfod01/trac/science/cumulative_guidance.pdf.

This document consists of six sections. Section I, Introduction, contains the regulatory framework for reregistration/tolerance reassessment. Section II, Chemical Overview, provides a profile of the use and usage of the chemical and its regulatory history. Section III, Summary of Diuron Risk Assessments, gives an overview of the revised human health and environmental effects risk assessments resulting from public comments and other information. Section IV, Risk Management: Reregistration and Tolerance Reassessment, presents the Agency's reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes label changes needed to implement the risk mitigation measures outlined in Section IV. The Appendices, provide information on how to access related documents, and list Data Call-In (DCI) information. The revised risk assessments and related addenda are not included in this document, but are available on the Agency's web page www.epa.gov/pesticides, and in the Public Docket.

II. Chemical Overview

A. Regulatory History

Diuron has been registered in the United States since 1967 for use as an herbicide, mildewcide and algaecide.

A Registration Standard, titled "Guidance for the Reregistration of Pesticide Products Containing Diuron as the Active Ingredient" was released in 1983. The Registration Standard involved a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that were considered insufficient. Subsequent Data Call-Ins (DCIs) were issued in 1990, and 1995 for diuron. This Reregistration Eligibility Decision (RED) reflects a reassessment of all data submitted to date.

There is a Section 18, Emergency Exemption registration for diuron use on catfish in the states of Arkansas, Louisiana, and Mississippi. The Agency is considering the catfish use for registration under Section 3 of FIFRA. Therefore, the risks from the catfish use have been assessed and are discussed in this document.

This Reregistration Eligibility Decision document evaluates risks from all currently registered uses, including agricultural food and non-food crops; ornamental trees, flowers, and shrubs; paints and coatings; ornamental fish and catfish production; rights-of-way and industrial sites. Residential uses include ponds, aquariums, and paints.

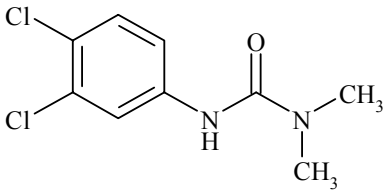
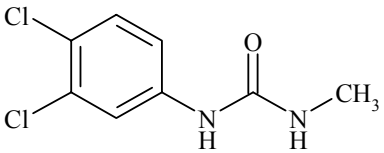
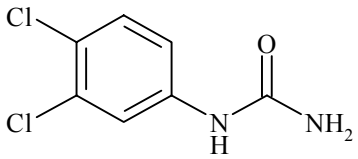
In an effort to promote transparency of the reregistration process and public acceptance of regulatory decisions, the Agency, in cooperation with the U.S. Department of Agriculture (USDA), is working to modify the reregistration process. An interim process has been established to provide opportunities for stakeholders to ask questions and provide input on the risk assessment and risk mitigation strategies, via conference calls and other formats. See Chapter IV, Section B for a detailed description of the modified process. A Tolerance Reassessment Progress and Risk Management Decision (TRED) was issued in July 2002. This RED document contains the tolerance reassessment decision as well as the Agency's decisions on the mitigation needed for other human health and environmental risks.

A risk mitigation meeting was held with stakeholders on August 6, 2003. Stakeholders and research organizations provided new information regarding use rates, acreage, application frequency, application equipment, etc., which enabled EPA to significantly refine the occupational risk assessment. Also, a close-out conference call was conducted on September 29, 2003, with EPA, USDA, the registrants, and other stakeholders (e.g., growers, commodity groups, land grant universities), to discuss the risk management decisions and resultant changes to the diuron labels.

B. Chemical Identification

The Agency has reviewed the metabolism of diuron in plants and animals from the results of wheat, corn, orange, ruminant, and poultry studies together with the environmental fate studies conducted in soil and water and has identified the following ^{14}C-containing residues in plants: diuron, 3,4-dichlorophenylurea (DCPU), and 3-(3,4-dichlorophenyl)-1-methylurea (DCPMU). No other dichloroaniline-containing metabolites were identified. The majority of radioactivity in the aqueous/organic fractions was characterized as polar unknowns. Radiovalidation of a GC/ECD data collection method which is similar to the enforcement method suggested that a good portion of these polar metabolites can be converted to 3,4-DCA. The chemical names and structures of these compounds are depicted in Figure A.

Figure A. Chemical structures of diuron residues of concern.

		
Diuron: 3-(3,4-dichlorophenyl)-1,1-dimethylurea	**DCPMU; IN-15654**: 3-(3,4-dichlorophenyl)-1-methylurea	**DCPU; IN-R915**: 3,4-dichlorophenylurea

- **Common Name:** Diuron
- **Chemical Name:** 3-(3,4-dichlorophenyl)-1,1-dimethylurea
- **Chemical Family:** dimethylurea
- **CAS Registry Number:** 330-54-1
- **OPP Chemical Code:** 035505
- **Empirical Formula:** $C_9H_{10}Cl_2N_2O$
- **Molecular Weight** 233.1
- **Vapor Pressure:** 2×10^{-7} mm Hg at 30 °C
- **Basic Manufacturer:** Griffin LLC

Table 1. Diuron Physical and Chemical Properties

Guideline Number	Physical and Chemical Property	Data
830-6302	Color	White
830-6303	Physical State	Crystal
830-6304	Odor	None
830-7200	Melting Point	158° C
830-7840	Water Solubility	42 ppm @ 25° C
830-7950	Vapor Pressure	2×10^{-7} mm Hg @ 30° C
830-7550	Partition Coefficient (Log P_{ow})	2.68
830-6320	Corrosion characteristics	Not corrosive
830-6313	Stability to normal and elevated temperatures, metals, and metal ions	Stable for 2 yrs. in double polyethylene bag inside a fiber drum under warehouse conditions. Metals and metal ion data not given.

C. Use Profile

The following is information on the currently registered uses including an overview of use sites and application methods. A detailed table of the uses of diuron eligible for reregistration is contained in Appendix A.

Type of Pesticide

Diuron is a substituted urea herbicide for the control of a wide variety of annual and perennial broad leaved and grassy weeds on both crop and non-crop sites. The mechanism of herbicidal action is the inhibition of photosynthesis.

Use Sites

Products containing diuron are intended for both occupational and residential uses. Occupational uses include agricultural food and non-food crops; ornamental trees, flowers, and shrubs; paints and coatings; ornamental fish ponds, and catfish production; rights-of-way and industrial sites. Residential uses include ponds, aquariums, and paints.

Use Limitations

The plantback intervals for the various crops on diuron labels range from 2 to 12 months. In addition, rotational crop restrictions are listed on individual labels, and further restrictions limit applications to crops grown in certain soils or soil types.

For more information about the plantback interval, please see the document titled, "Residue Chemistry Chapter For The Diuron Reregistration Eligibility Decision (RED) Document," dated 7/29/2001.

Target Pests

Diuron is used for pre-emergence control of annual grass and broadleaf weeds and some perennial weeds.

Formulation Types

Formulated as wettable powder (25% to 80% ai), liquid (up to 40% ai), emulsifiable concentrate (2% to 80% ai), dry flowable (40% to 80 % ai), flowable concentrate (19% to 47.5% ai), granular (0.2% to 20% ai), pellet/tablet (0.51% to 19% ai), and ready-to-use solution (0.67% to 19% ai).

Methods and Rates of Application

Diuron is applied using the following equipment: groundboom sprayer, aerial equipment, chemigation, rights-of-way sprayer, high-pressure handwand, low-pressure handwand, tractor-drawn spreader, granular backpack spreader, push-type spreader, airless sprayer, paintbrush, shaker-type applicator, backpack sprayer, belly grinder, and by hand. Products intended for residential use may be applied using a spoon, by hand, by airless sprayer, or by paintbrush/roller.

For agricultural uses, labeled single application rates range from 0.2 to 6.4 lbs active ingredient (ai) per acre (A). For citrus, a yearly maximum of 9.6 lbs ai/A is on current labels. For non-agricultural uses labeled rates range from 0.8 lbs to 87 lbs ai/acre; however, the highest application rate on an actively marketed label is 12 lbs ai/acre. The risk assessments evaluate a range of rates; however, this overview will focus on application rates of 12 lbs ai/A or lower. The higher rates on the other products are not being supported by the registrant and will be removed from product labels. Diuron may be applied to non-agricultural areas 1 to 2 times per year. For the mildewcide and preservative in paint uses, label rates go up to 0.053 lbs ai/gal. and for algaecidal uses labeled rates are less than 1/100th % ai/gal.

Timing of Application

One to four applications per season may be applied in 60-day intervals (on current labels); for most uses only one application is used.

D. Estimated Usage of Pesticide

Estimates for total annual domestic use of diuron average approximately nine to ten million pounds of active ingredient. Approximately two thirds are used on agricultural crops and the remaining one third on non-crop areas. Crops with the highest percent crop treated are the citrus, various berries, pineapple, and asparagus. In terms of pounds applied, oranges and cotton account for the greatest agricultural use. Right-of-way applications (e.g., the area around railroad tracks) are the greatest non-agricultural use of diuron, with approximately 2 to 3 million pounds applied annually. These estimates were derived from a variety of published and proprietary sources available to the Agency. Table 2 summarizes the best available estimates for the pesticide usage of diuron.

Table 2. Diuron Crop Usage Summary

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		Pounds AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	Pounds ai/ Acre Per Year	Pounds Applied Per Year	Pounds ai Per Acre Applied	(% of total lb ai used on this site)
Blackberries	5	3	4	53%	73%	5	7	1.7	1.1	1.5	OR 100%
Blueberries	59	17	22	29%	37%	21	29	1.2	1.1	1.1	MI NJ OR 84%
Raspberries	13	2	4	13	29	2	4	1.2	1.1	1.1	WA OR 100%
Grapes	869	87	155	10	18	100	200	1.2	1.0	1.2	CA NY PA 81%
Grapefruit	189	89	147	47	78	240	462	2.7	1.7	1.6	FL TX 92%
Lemons	67	18	35	26	53	39	86	2.2	1.3	1.7	CA AZ 98%
Oranges	927	470	578	51	62	1,210	1,710	2.6	1.7	1.5	FL CA 97%
Citrus, Other	62	24	39	38	63	65	118	2.8	1.7	1.6	FL AZ 93%
Limes	6	2	3	33	49	5	7	2.4	1.8	1.3	-
Tangelos	12	6	7	47	58	17	26	2.9	2.1	1.4	FL 100%
Tangerines	37	11	16	30	43	22	31	2.0	1.7	1.1	FL CA 100%
Temples	7	3	5	51	80	9	18	2.6	1.9	1.4	FL 100%
Apples	520	65	113	13	22	100	188	1.5	1.1	1.4	NY WA PA ID OH 65%
Pears	74	7	15	9	20	15	31	2.2	1.2	1.8	OR CA WA 81%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		Pounds AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	Pounds ai/ Acre Per Year	Pounds Applied Per Year	Pounds ai Per Acre Applied	(% of total lb ai used on this site)
Pome Fruit, Other	31	4	6	13	19	10	15	2.6	1.8	1.5	FL 98%
Avocados	80	1	2	1	2	1	3	1.7	1.3	1.3	FL 100%
Cherries, Sweet	52	0.2	0.8	0.3	2	0.3	1.7	2.1	1.9	1.1	MI OR 93%
Cherries, Tart	49	1	4	3	8	3	9	2.1	1.2	1.8	MI 88%
Nectarines	36	0.1	0.5	0.3	1	0.2	0.8	1.6	1.0	1.6	-
Olives	36	8	12	24	35	14	19	1.6	1.2	1.4	-
Peaches	260	25	56	10	21	38	81	1.5	1.0	1.4	GA SC NJ PA WV CA 74%
Plums/Prunes	147	4	6	3	4	2	3	0.6	1.2	0.5	CA OR GA 85%
Almonds	489	3	10	1	2	6	15	2.2	1.2	1.8	CA 100%
Hazelnuts/Filberts	29	4	8	14	28	5	9	1.2	1.0	1.2	OR 100%
Macadamia & Pistachio	75	4	7	5	10	9	18	2.5	2.4	1.0	-
Pecans	452	13	26	3	6	28	58	2.1	1.0	2.1	GA AZ NM CA 80%
Walnuts	215	26	43	12	20	51	98	2.0	1.1	1.8	CA 98%
Asparagus	83	45	56	53	68	74	80	1.7	1.2	1.3	CA MI WA 96%
Barley	6612	8	38	0.1	1	1	6	0.2	1.0	0.2	-
Corn	77779	19	79	0.02	0.1	18	83	0.9	1.0	0.9	LA MS PA TX 87%
Mint	167	68	91	41	54	22	29	0.3	-	-	CA ID 90%
Oats	2667	3	8	0.1	0.3	2	5	1.6	-	-	OR WA 100%
Seed Crops	1249	547	683	44	55	678	848	1.2	-	-	OR ID 88%
Sorghum	10216	14	52	0.1	1	9	37	0.6	1.0	0.6	TX NM 91%
Sugarcane	882	36	76	4	9	42	89	1.2	1.1	1.0	LA 93%
Wheat, Spring	20599	14	38	0.1	0.2	8	20	0.5	1.0	0.5	ID OR 88%
Wheat, Winter	43721	150	319	0.3	1	140	380	0.9	1.0	0.9	OR OK WA 87%
Alfalfa	23665	190	380	1	2	240	350	1.3	1.0	1.3	CA KS AZ NV MT 81%
Hay, Other	25983	30	81	0.1	0.3	36	95	1.2	1.0	1.2	CA TX KS OR NC 81%
Cotton	13188	1450	2322	11	18	770	1224	0.5	1.3	0.4	TX MS LA AR GA 85%

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		Pounds AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	Pounds ai/ Acre Per Year	Pounds Applied Per Year	Pounds ai Per Acre Applied	(% of total lb ai used on this site)
Cropland for Pasture	63687	3	6	-	-	4	8	1.3	1.0	1.3	OR CA 80%
Pasture/Rangeland, Other	358724	26	78	0.01	0.02	62	187	2.4	1.0	2.4	OR 83%
Fallow, Summer	24699	17	52	0.1	0.2	10	29	0.6	1.0	0.6	NE TX 84%
Idle Cropland, Other	7366	4	13	0.1	0.2	9	28	2.1	1.1	1.8	OR 92%
Lots/Farmsteads/Etc.	23987	21	37	0.1	0.2	66	134	3.1	1.3	2.4	CA AR WA UT OR NC 70%
Building/Structures	-	-	-	-	-	2	5	-	-	-	-
Roads/Ditches/ Misc.	-	-	-	-	-	64	129	-	-	-	-
Ornamentals	-	47	70	-	-	54	80	1.2	1.1	1.1	OR CA MT 87%
Non-Farm											
Industrial Facilities/ Pipelines	4312	-	-	-	-	518	1047	-	-	615	-
Wholesale/ Manufacturing	30149	-	-	-	-	166	218	-	-	-	-
Lawn/ Landscape Operator	30419	-	-	-	-	46	100	-	-	2.0	-
Residential	-	-	-	-	-	13	25	-	-	-	-
Office/Retail (for hire)	-	-	-	-	-	28	42	-	-	-	-
Nurseries/ Greenhouses	409	8	24	2	6	10	29	1.2	1.0	1.2	-
Office/Retail (not for hire)	-	-	-	-	-	71	106	-	-	-	-
Pest Control Operator	-	5	15	-	-	-	-	-	-	-	-
Railroads	1577	-	-	-	-	2,007	2,907	-	-	4.7	-
Recreation	-	-	-	-	-	12	23	-	-	-	-
Roadways	11400	-	-	-	-	426	800	-	-	2.3	-
Sanitation/Utilities	-	-	-	-	-	617	1051	-	-	-	-
Electric Utilities	9669	-	-	-	-	167	288	-	-	3.6	-
Crops Grown Outside the Continental United States With Limited Usage Data											
Pineapple				no data	no data						

Site	Acres Grown (000)	Acres Treated (000)		% of Crop Treated		Pounds AI Applied (000)		Average Application Rate			States of Most Usage
		Wtd Avg	Est Max	Wtd Avg	Est Max	Wtd Avg	Est Max	Pounds ai/ Acre Per Year	Pounds Applied Per Year	Pounds ai Per Acre Applied	(% of total lb ai used on this site)
Bananas				14	18						
Papaya				13	19						
Total						7,914	10,429				

COLUMN HEADINGS
Wtd. Avg. = Weighted average--the most recent years and more reliable data are weighted more heavily.
Est. Max. = Estimated maximum, which is estimated from available data.
Average application rates are calculated from the weighted averages.

NOTES ON TABLE DATA
Usage data primarily covers 1990 - 1999.
Calculations of the above numbers may not appear to agree because they are displayed as rounded to the nearest 1,000 for acres treated or lb. a.i. (therefore 0 = < 500), and rounded to one decimal percentage point for % of crop treated and pounds of a.i..
SOURCES: EPA, USDA , and National Center for Food and Agricultural Policy.

III. Summary of Diuron Risk Assessment

The following is a summary of EPA's human health and ecological risk findings and conclusions for diuron, as presented fully in the documents, "Diuron: the Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)," dated July 9, 2003, "Environmental Risk Assessment for the Reregistration of Diuron," dated August 27, 2001, and “Surface Water Monitoring Data for Diuron,” dated August 5, 2003. Since the completion of the preliminary risk assessments, the Agency has calculated new surface water concentrations for diuron based on monitoring data. Also, new information provided by stakeholders enabled the Agency to characterize worker cancer risk estimates.

The purpose of this section of the decision document is to summarize the key features and findings of the risk assessment in order to help the reader better understand the risk management decisions reached by the Agency. While the risk assessments and related addenda are not included in this document, they are available in the public docket.

A. Human Health Risk Assessment

Risks from dietary exposure (food and drinking water), residential exposure, aggregate exposures, and occupational exposures have been evaluated for diuron.

1. Dietary Risk From Food

a. Toxicity

The toxicity database for diuron is adequate to assess the potential hazard to humans, including special sensitivity of infants and children. The database will support a reregistration eligibility decision for the currently registered uses. However, EPA is requiring that a 28-day

inhalation study be submitted to address the concern for inhalation exposure potential based on the use pattern. For more information on the toxicity of diuron, please see the document titled "Diuron - Phase 2: Revised Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision," dated March 6, 2002.

Acute Toxicity:

Diuron has low acute toxicity (Toxicity Category 3 or 4) by the oral, dermal, or inhalation exposure routes. Diuron is not an eye or skin irritant, and not a skin sensitizer. A rat metabolism study indicated that diuron is rapidly absorbed and metabolized within 24 hours post-dose at the low dose and within 48 hours post-dose at the high dose. The urine is the major route of excretion in both sexes. A small amount of diuron is detected in the feces. The highest tissue residue levels were found in the liver and kidneys 4 days post ^{14}C-diuron dose. The metabolism of diuron involved N-oxidation, some ring hydroxylation, demethylation, dechlorination, and conjugation to sulfate and glucuronic acid. Acute toxicity values and categories for the technical grade of diuron are summarized in Table 3.

Table 3. Acute Toxicity of Diuron

Guideline No.	Study Type	Results	Toxicity Category
870.1100	Acute Oral	LD_{50} = 4721 mg/kg (M) >5000 mg/kg (F)	III
870.1200	Acute Dermal	LD_{50} >2000 mg/kg	III
870.1300	Acute Inhalation	LC_{50} >7.1 mg/L	IV
870.2400	Primary Eye Irritation	At 48 hrs, all irritation had cleared.	III
870.2500	Primary Skin Irritation	All irritation had cleared by 72 hrs.	IV
870.2600	Dermal Sensitization	Nonsensitizer	N/A
870.6200	Acute Neurotoxicity	Not available	N/A

Subchronic/Chronic Systemic Toxicity: The primary diuron target sites are blood, bladder, and kidney. Erythrocyte (red blood cell) damage resulted in hemolytic anemia and compensatory hematopoiesis, which are manifested as significantly decreased erythrocyte counts, hemoglobin levels, and hematocrit, and increased mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), abnormal erythrocyte forms, reticulocyte counts, and leukocyte count. Consistent observations of erythocytic regeneration are seen in chronic toxicity studies in rats, mice and dogs. Gross pathology findings in chronic rat and mouse studies showed increased incidences of urinary bladder swelling and wall thickening at high doses. Microscopic evaluation showed dose-related increases in the severity of epithelial focal

hyperplasia of the urinary bladder and renal pelvis (kidney) in both sexes.

Although the developmental toxicity study in rats is classified as unacceptable, the data base as a whole is adequate for pre- and post-natal toxicity evaluation and did not reveal developmental or reproductive toxicity. The NOAELs for maternal/parental toxicity were either less than or equal to the NOAELs for fetal or reproductive toxicity. A complete summary of the toxicity database is discussed in the document titled "Diuron - Phase 2: Revised Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision," dated March 6, 2002.

Carcinogenicity: Diuron has been characterized as a "known/likely" human carcinogen, based on urinary bladder carcinomas in both sexes of the Wistar rat, kidney carcinomas in the male rat (a rare tumor), and mammary gland carcinomas in the female NMRI mouse. The Agency has used a low dose linear extrapolation model with a Q_1^* of 1.91×10^{-2} $(mg/kg/day)^{-1}$ to be applied to the animal data for the quantification of human risk, based on the urinary bladder carcinomas in the rat. Tumors were observed only at doses in excess of 600 mg/kg/day.

Mechanism of Carcinogenicity: The registrant has requested that the Agency reconsider the 1996 carcinogenicity assessment for the following reasons: 1) there is a plausible mode of action that discounts the relevance of the rat bladder carcinomas to humans, 2) the mouse historical data were not considered in their entirety and should be considered 'spontaneous," 3) the structure activity relationships actually decrease the weight-of-the-evidence of diuron carcinogenicity rather than increase the weight, 4) new guidelines are in place that separate the 'known' from 'likely' category and 5) there is no history of human carcinogenesis as a result of diuron exposure.

The Agency reviewed the submitted information/data and mutagenicity studies, considered the registrant's proposed mechanism of action and determined that diuron will not be re-classified at this time. The Agency based its decision on: 1) the registrant did not submit any data or information to support its claim that there is no evidence of human carcinogenesis; 2) the submitted information is insufficient to support a mode of action on bladder carcinogenicity for diuron; 3) the mouse historical data have been reviewed - the Agency concluded that a positive oncogenic response was seen in high-dose female mice compared to the control group; 4) there is insufficient evidence to support the notion that the structure activity relationships actually decrease the weight-of-the-evidence of diuron carcinogenicity rather than increase the weight; and 5) preliminary reviews have been conducted on newly submitted *in vivo* cytogenetic mutagenicity studies (mouse bone marrow micronucleus assays) and no evidence of cytogenetic effect was seen in mice administered either technical grade or formulated diuron. However, these studies provide little additional information since EPA has already concluded that there is little or no concern for the mutagenic activity of diuron. The registrant has indicated their intention to submit a study on the cancer mechanism of action for diuron. The study is scheduled for completion in 2004 and will be submitted to the Agency for further consideration.

Mutagenicity: Diuron was not mutagenic in bacteria or in cultured mammalian cells and no indication of DNA damage in primary rat hepatocytes was observed. There were marginal statistically significant increases in cells with structural aberrations in a Sprague Dawley rat *in vivo* bone marrow chromosomal aberration assay. However, the levels of aberrations were within the historical control range and assessed negative.

Developmental/Reproductive Toxicity: There is an acceptable developmental toxicity study in rabbits and an acceptable two-generation reproduction study in rats. A developmental toxicity study in rats was classified as unacceptable due to deficiencies in analytical data on the sample analysis; however, the Agency considered the developmental toxicity study in rats adequate for the FQPA susceptibility assessment based on the observation that the developmental toxicity NOAEL was higher than the maternal NOAEL and concluded that a developmental neurotoxicity (DNT) study is not required.

There is no indication of increased susceptibility to young exposed to diuron in the available studies. In the developmental toxicity study in rabbits, there were no developmental effects at the highest dose tested. In the developmental toxicity study in rabbits and in the 2-generation rat reproduction study, developmental/offspring effects were observed only at maternally/parentally toxic dose levels.

Neurotoxicity: No acute or subchronic neurotoxicity data are available. However, there are no neurotoxic signs in any of the submitted subchronic or chronic studies and a literature search did not reveal any studies relevant for assessing the potential neurotoxicity of diuron.

Dermal Absorption: No systemic toxicity was seen following repeated dermal dosing at 1200 mg/kg/day in the rabbit dermal toxicity study. An upper-bound estimation of dermal absorption of 4% was extrapolated using the maternal LOAEL of 50 mg/kg/day from the oral developmental toxicity study in the rabbit and the NOAEL of 1200 mg/kg/day (HDT) from the 21-day dermal toxicity study in the rabbit: the ratio is 50/1200 or 4%.

b. FQPA Safety Factor

The FQPA safety factor is intended to provide up to an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food. The FQPA Safety Factor Committee concluded that the safety factor could be removed (i.e., reduced to 1x) for diuron for the following reasons:

- There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure;
- A DNT study with diuron is not required; and
- The dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for infants and children.

c. Endpoints and Doses for Risk Assessment

The doses, toxicity endpoints selected and supporting studies for various exposure scenarios are summarized in Table 5.

Table 5. Summary of Doses and Toxicological Endpoints for Diuron

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	No appropriate endpoint attributed to a single dose was identified. Therefore, an acute RfD was not established.		
Chronic Dietary	LOAEL = 1.0 UF = 300 FQPA SF = 1	Evidence of hemolytic anemia and compensatory hematopoiesis (significantly decreased erythrocyte counts, hemoglobin levels, and hematocrit, and increased MCV, MCH, abnormal erythrocyte forms, reticulocyte counts, and leukocyte count)	Combined chronic toxicity/carcinogenicity study in rats MRID 40886501, 43871901, 43804501, 44302003
		Chronic RfD = 0.003 mg/kg/day cPAD = 0.003 mg/kg/day	
Incidental Oral, short-term (1-30 days)	NOAEL= 10 UF = 100 FQPA SF = 1	Decreased body weight and food consumption at maternal LOAEL of 50 mg/kg/day.	Developmental toxicity study in rabbits MRID 40228802
	Level of Concern for residential MOE = 100		
Incidental Oral, Intermediate-Term (1-6 months)	NOAEL = 1.0 UF = 100 FQPA SF = 1	Altered hematological parameters at LOAEL of 10 mg/kg/day, observed at 6 months.	Chronic toxicity/carcinogenicity study in rats MRID 40886501, 43871901, 43804501, 44302003
	Level of Concern for residential MOE = 100		
Dermal, Short-Intermediate-Term	No systemic toxicity was seen following repeated dermal dosing at 1200 mg/kg/day in the rabbit dermal toxicity study. No hazard was identified and no quantitative assessment is required.		
Dermal, Long-Term (6 months to life-time) Absorption factor of 4% used for conversion from oral to dermal route	LOAEL = 1.0 UF = 300 FQPA SF = 1	Evidence of hemolytic anemia and compensatory hematopoiesis (significantly decreased erythrocyte counts, hemoglobin levels, and hematocrit, and increased MCV, MCH, abnormal erythrocyte forms, reticulocyte counts, and leukocyte count).	Chronic toxicity/carcinogenicity study in rats MRID 40886501, 43871901, 43804501, 44302003
	Level of Concern for occupational/residential MOE = 300		
Inhalation, Short-Term (1-30 days)	NOAEL = 10 UF = 100 FQPA SF = 1	Decreased body weight and food consumption at maternal LOAEL of 50 mg/kg/day.	Developmental toxicity study in rabbits MRID 40228802

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
	Level of Concern for occupational/residential MOE = 100		
Inhalation, Intermediate-Term (1-6 months)**	NOAEL = 1.0 UF = 100 FQPA SF = 1	Altered hematological parameters at LOAEL of 10 mg/kg/day, observed at 6 months.	Chronic toxicity/carcinogenicity study in rats MRID 40886501, 43871901, 43804501, 44302003
	Level of Concern for occupational/residential MOE = 100		
Inhalation, Long-Term (6 months to life-time)**	LOAEL = 1.0 UF = 300 FQPA SF = 1	Evidence of hemolytic anemia and compensatory hematopoiesis (significantly decreased erythrocyte counts, hemoglobin levels, and hematocrit, and increased MCV, MCH, abnormal erythrocyte forms, reticulocyte counts, and leukocyte count).	Chronic toxicity/carcinogenicity study in rats MRID 40886501, 43871901, 43804501, 44302003
	Level of Concern for occupational/residential MOE = 300		
Cancer	Known/likely human carcinogen	Urinary bladder carcinoma in both sexes of the Wistar rat, kidney carcinomas in the male rat (a rare tumor), and mammary gland carcinomas in the female NMRI mouse	Carcinogenicity studies in rats and mice MRID 40886501, 43871901, 43804501, 44302003 and 42159501, 43349301
	$Q_1^* = 1.91 \times 10^{-2}$ (mg/kg/day)$^{-1}$		

UF = Uncertainty Factor
PAD = Population Adjusted Dose (includes UF and FQPA safety factor)
MOE = Margin of Exposure

d. Endocrine Disruption

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, diuron may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

At this time, neither the available submitted studies on diuron nor the literature show any indication of endocrine disruption effects.

e. 3,4-dichloroaniline (3,4-DCA)

3,4-dichloroaniline (3,4-DCA) is a metabolite of diuron as well as two other pesticides, linuron and propanil. However, EPA's Metabolism Assessment Review Committee (MARC) concluded that residues of 3,4-DCA should not be aggregated for the diuron, linuron, and propanil risk assessments because 3,4-DCA is significant residue of concern for propanil, but is not a residue of concern per se for diuron or linuron. Although the analytical method for quantifying residues of concern from diuron converts all residues to 3,4-DCA as a convenience, 3,4-DCA was not a significant residue in any metabolism or hydrolysis study.

f. Potential Tetrachloroazobenzene Contamination

Diuron has been reported to contain trace amounts of a manufacturing impurity, 3,3',4,4'-tetrachloroazobenzene, (TCAB), which has been shown to be a cytochrome P450 enzyme inducer. A summary of short-term bioassays compiled by the National Toxicology Program states that (*TOX-65, 1998*),

> "3,3',4,4'-tetrachloroazobenzene caused typical dioxin-like effects, such as thymic atrophy, an increase in liver weights, induction of hepatic cytochrome P4501A, and decreased mean body weight gains. Furthermore, in the 13-week studies, a sharp decrease in circulating thyroxine concentrations was observed even at the lowest dose (0.1 mg/kg) tested in rats. Other effects included a decrease in epididymal spermatozoal concentration in mice, major effects on the hematopoietic system, and increased incidence of hyperplasia of the forestomach in 3 and 30 mg/kg males and 30 mg/kg females. A no-observable-adverse-effect-level (NOAEL) was not reached in rats. The NOAEL in mice was 0.1 mg/kg. Comparison of various dioxin-like effects in these studies with those reported in the literature indicate that 3,3',4,4'-tetrachloroazobenzene is two to six orders of magnitude less potent than 2,3,7,8-tetrachlorodibenzo-p-dioxin."

Chronic toxicity/carcinogenicity studies are not available for TCAB. The specific endpoint(s) and related dose levels that may be observed in chronic toxicity studies, or the specific carcinogenic potential of this compound is not known. However, since it is assumed that TCAB may have been present in all diuron toxicological test materials, including the test material for the chronic toxicity/carcinogenicity studies, the Agency concludes that the risks from exposure to diuron and TCAB resulting from use of diuron products (including carcinogenic potential) have not been underestimated.

g. Exposure Assumptions

Diuron is not acutely toxic. No adverse effects attributed to a single exposure were identified in any available study. Therefore, no acute dietary risk assessment was conducted. A chronic exposure analysis for diuron and its metabolites that are hydrolyzable to 3,4-DCA was performed utilizing the Dietary Exposure Evaluation Model (DEEM^{TM}) software Version 7.73. DEEM^{TM}, developed by Novigen Sciences, Inc. This model calculates acute and chronic dietary

exposure and risk estimates for residues in food for the U.S. general population and various population subgroups. The software contains food consumption data from the USDA Continuing Survey of Food Intake by Individuals (CFSII) from 1989-1992. For chronic and cancer dietary risk assessments, the 1989-1992 data are based on the reported consumption patterns of more than 10,000 individuals over three consecutive days, and therefore represent more than 30,000 unique "person days" of data. Foods "as consumed" (e.g. apple pie) are linked to raw agricultural commodities and their food forms (e.g. apples cooked/canned or wheat flour) by proprietary recipe translation files within DEEM. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment. For chronic exposure and risk assessment, an estimate of the residue level in each food or food form (e.g. orange or orange juice) on the commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total estimated exposure. The calculated chronic exposure (residue x consumption) was compared to a cPAD of 0.003 mg/kg/day, which reflects an FQPA factor of 1x. Noncancer dietary exposure estimates are expressed in milligrams per kilogram of body weight per day (mg/kg/day).

Diuron is used on a wide variety of food and feed crops. Residue levels from United States Department of Agriculture (USDA) and Food and Drug Administration (FDA) monitoring programs do not include all the residues of concern needed for the Agency's diuron risk assessment (diuron and metabolites convertible to 3,4-DCA) and were not used for this analysis. Instead, anticipated residues (ARs) from field trial data were utilized to estimate the dietary exposure to diuron from the diets of the U.S. population as well as certain population subgroups. The field trials were conducted at the highest application rates for the crop tested and therefore, the residues from these trials are considered high end.

Available processing data for apple, citrus and grapes indicated that there was no concentration, nor reduction, in residue values for these processed commodities (i.e., juice, dried fruit). The sugarcane processing study showed a reduction of residues in refined sugar but a concentration of residues in molasses. With the exception of residue data from the processing of sugarcane into refined sugar and molasses, the only additional refinements to the residue data are the use of averaged percent crop treated (%CT) information.

Percent crop treated data were available for blackberries, blueberries, raspberries, grapes, grapefruit, lemons, oranges, limes, tangelos, tangerines, temples, apples, pears, avocados, sweet cherries, tart cherries, nectarines, olives peaches, plums/prunes, almonds, hazelnuts, macadamia nuts, pistachio nuts, pecans, walnuts, asparagus, barley corn, mint oats, seed crops, sorghum, sugarcane, wheat, alfalfa, hay, cotton, cropland for pasture, pasture/rangeland, fallow, idle cropland, lots/farmsteads, and nurseries/greenhouses. These data were used for the chronic dietary assessment.

The reregistration requirements for magnitude of the residue in plants are not fulfilled for: alfalfa forage; globe artichoke; barley hay; cotton gin byproducts; field corn aspirated grain fractions; field corn forage and stover; filbert; grass forage, hay, seed screenings, and straw; lemon; pear; oat forage, hay; olive; field pea vines and hay; sorghum aspirated grain fractions, stover, and forage; wheat forage and hay. Additional crop field trial data are required for these commodities.

h. Dietary (Food) Risk Assessment

(1) Acute Dietary Risk

There are no adverse effects attributed to a single exposure identified in any available studies. In addition, diuron has low acute toxicity and no developmental or neurotoxic concerns. Therefore, no acute dietary endpoint was chosen and no acute dietary risk assessment was conducted.

(2) Chronic (Non-Cancer) Dietary Risk

Chronic dietary risk is calculated by using an average consumption value for food and average residue values on those foods consumed over a 70-year lifetime. A risk estimate that is less than 100% of the chronic PAD (the dose at which an individual could be exposed over the course of a lifetime and no adverse health effects would be expected) does not exceed the Agency's level of concern. The cPAD is the chronic reference dose (cRfD) adjusted for the FQPA Safety Factor.

As shown in Table 6, non-cancer chronic risk estimates for all population subgroups are below the Agency's level of concern (<100% cPAD). Estimated chronic dietary (food) risk estimates associated with the use of diuron do not exceed the Agency's level of concern (> 100% cPAD) for any population subgroup including the most highly exposed population subgroup, children ages 1-6 years. The chronic dietary risk for children ages 1-6 years is 7% of the chronic PAD and 3% for the general U.S. population. Orange juice and orange juice concentrate are the largest contributors to dietary exposure from diuron.

Table 6. Summary of Chronic Dietary Exposure and Risk for Diuron

Population	Exposure mg/kg/day	% Chronic PAD
U.S. Population	0.000088	3
All Infants (<1 year)	0.000077	3
Children 1-6 years	0.00020	7
Children 7-12 years	0.000118	4
Females 13-50 years	0.000069	2
Males 13-19 years	0.000098	3
Males 20+ years	0.000066	2
Seniors 55+ years	0.000083	3

(3) Cancer Dietary Risk from Food

Like chronic dietary risk, potential dietary cancer risk is calculated by using the average consumption values for food and average residue values for those foods over a 70-year lifetime. The chronic exposure value is typically combined with a linear low-dose (Q_1*) approach to determine the lifetime (cancer) risk estimate. The Agency generally considers risks greater than 1×10^{-6} (i.e., probability greater than one in one million) to be of potential concern for dietary cancer exposure. Table 7 presents the lifetime (70 year) cancer risk estimates for the U.S. general population. The estimated cancer dietary risk associated with the use of diuron indicates a borderline exceedance above 1×10^{-6} and shows a lifetime risk estimate of 1.68×10^{-6} for the general population but, is not of concern. As discussed earlier, the residues used in the calculations are from field trials conducted at the highest application rates and some processing data are still outstanding. Therefore, the exposure calculation is a conservative estimate. Again, the Agency assumed that exposure was to diuron and its metabolites that are hydrolyzable to 3,4-DCA.

Table 7 . Summary of Diuron Dietary Exposure and Risk

Population	Acute Dietary	Chronic Dietary		Cancer Dietary	
	NA	Exposure (mg/kg/day)	Risk (% cPAD)	Exposure (mg/kg/day)	Lifetime Risk (Q_1*= 0.0191)
U.S. Population		0.000088	3	0.000088	1.68×10^{-6}
All Infants < 1 year		0.000077	3	Not Applicable	
Children 1-6 years		0.000200	7		
Children 7-12 years		0.000118	4		
Females 13-50 years		0.000069	2		

MCPDMU Cancer Dietary Risk

Environmental laboratory studies have shown that in drinking water only, diuron partially degrades to another chemical referred to as MCPDMU (N'-(3-chlorophenyl)-N,N-dimethyl urea). However, the environmental fate and persistence of MCPDMU are uncertain. MCPDMU is structurally similar to monuron [N'-(4-chlorophenyl)-N,N-dimethyl urea], a pesticide no longer registered in the United States. Monuron produces tumors in the kidney and liver in male rats and has a Q_1* of 1.52×10^{-2}. Due to the structural similarity between MCPDMU and monuron, the Agency believes it is prudent to evaluate the carcinogenic risk associated with MCPDMU based upon the hazard information concerning the chemical monuron. The Agency believes MCPDMU is likely less toxic than monuron, but is unable to quantify this difference without further information. The approach used in this assessment yields a high-end estimate. Absent information specifically about the carcinorgenic potential of MCPDMU, the Agency has taken this conservative, health protective approach in its assessment. The Agency is addressing this uncertainty by requiring additional information about the behavior and fate of diuron and its drinking water degradate, MCPDMU.

Two separate cancer risk assessments were completed for diuron and MCPDMU (N'-(3-chlorophenyl)-N,N-dimethyl urea), a degradate of diuron in water only. Because the cancer effects (i.e., target organs) for the two compounds differ, the risks from diuron and MCPDMU are not combined.

Based on a Q_1* of a similar compound, monuron, the estimated dietary risk for MCPDMU is 1.02×10^{-7}, which includes catfish consumption only. The anticipated residue of MCPDMU in catfish was calculated using the 2 ppm tolerance for catfish, the fraction of applied radioactive diuron converted to MCPDMU in an aerobic aquatic metabolism study (see the Environmental Risk Assessment) and the percent crop treated for catfish.

2. Dietary Risk from Drinking Water

Drinking water exposure to pesticides can occur through ground and surface water contamination. EPA considers acute (one day) and chronic (lifetime) drinking water risks and uses either modeling or actual monitoring data, if available, to estimate those risks. For diuron, monitoring data were available for states with a high percent of diuron use. Therefore, monitoring data from Florida and California were used to estimate surface water concentrations, and SCI-GROW was used to estimate groundwater concentrations. The Screening Concentration in Ground Water Program (SCI-GROW), model is considered a screening tool.

To determine the maximum allowable contribution of pesticide residue in water allowed in the diet, EPA first looks at how much of the overall allowable risk is contributed by food, then calculates a drinking water level of comparison (DWLOC) to determine whether modeled or monitoring levels exceed this level.

The DWLOC represents the maximum contribution to the human diet (in ppb or µg/L) that may be attributed to residues of a pesticide in drinking water after dietary exposure is subtracted from the aPAD or cPAD. Risks from drinking water are assessed by comparing the DWLOCs to the estimated environmental concentrations (EECs) in surface water and ground water. Drinking water modeling is considered to be an unrefined assessment and provides conservative estimates based on maximum labeled rates and number of applications.

Neither diuron nor monuron are regulated under the Safe Drinking Water Act. As a result, neither Maximum Contaminant Levels (MCLs) nor drinking water health advisories (HAs) for these chemicals have been established by the EPA Office of Water. However, diuron was placed on a list of contaminants to be monitored during 2001 and 2002. This information will be used to support EPA decisions concerning whether or not to regulate and establish standards for diuron in drinking water.

a. Surface Water

In this case, only chronic (non-cancer) and cancer drinking water risks have been assessed since no acute endpoint was identified.

Diuron can be transported to surface water at application via run-off and spray drift from aerial and ground applications. In the preliminary assessment for surface water, chronic and cancer drinking water risks were potentially of concern based on modeled estimates. Based on information gathered after the initial risk assessment was prepared, the Agency has decided to use surface water monitoring data to estimate risks from drinking water. Conservative models were used to determine that the diuron degradates would add an additional 20 percent to the concentration of the parent compound. The drinking water assessment includes surface water monitoring data from Florida, the scenario which is anticipated to represent the highest potential drinking water concern. The following information was used in the revised surface water assessment.

- South Florida Surface Water Monitoring Data

  Data collected by the South Florida Water Management District (SFWMD) between December, 1998 and August, 2001 indicate that diuron was detected in only 17 of 438 samples (4% detection rate). The 37 monitoring stations were in south Florida, from Lake Okeechobee south to the Everglades. Diuron is used on citrus, bananas, and sugarcane in this area. The highest reported concentration was 1.2 ppb. The 90^{th} and 95^{th} percentile concentrations were below the detection limit (0.2 to 0.4 ppb). The data are available at www.sfwmd.gov/curre/pest/pestindex.htm.

- US Geological Survey (USGS) National Water Quality Assessment Program (NAWQA) data for Southeastern U.S.

  USGS NAWQA data for 3 study units (South Florida, Georgia-Florida Coastal Plain, and Appalachicola-Chattahoochee-Flint River) show a 22% detection rate (185 of 858 samples) for diuron over the period 1993 to 1998. Most of the latter study area was around Atlanta. All detects were less than or equal to 1 ppb. The median, 90^{th} percentile, and 95^{th} percentile concentrations were 0.05 ppb. The 99^{th} percentile was approximately 0.3 ppb. The detection limit was 0.02 ppb, about ten times lower than SFWMD's detection limit of 0.2 to 0.4 ppb, which may explain the higher detection rate.

- NAWQA Data

  The USGS NAWQA Program collected 1420 surface water samples from 62 agricultural stream sites during a 6 year period from 1992 - 1998. Diuron was detected in 7.32% of the samples at a mean concentration of 0.13 ppb.

- California Dormant Spray Monitoring Study

  The California Department of Pesticide Regulation (DFR) conducted a Dormant Spray Monitoring Study at three locations (82 samples) in the Sacramento River and two locations (54 samples) in the San Joaquin River, over the period December 2000 to March 2001. About one million pounds of diuron are used in these two watersheds per year. Diuron is used on a number of crops in California, including alfalfa, oranges, grapes, walnuts, asparagus, lemons, olives, cotton, grapefruit, and tangerines. Non-agricultural uses include rights-of-way, landscape maintenance, and uncultivated areas.

Each of the five locations was sampled at least once a week. 100% of the samples on the San Joaquin River had detectable diuron, with a maximum concentration of 8.45 ppb in the Orestimba Creek tributary. The average concentration at the two San Joaquin River stations was 1.7 ppb. About 75% of the samples in the Sacramento River had detectable diuron. The

maximum concentration was 1.42 ppb at the Alamar Marina dock, 9 miles downstream of the confluence of the Feather River. The average concentration, assuming that all non-detects were equal to the detection limit of 0.05 ppb, was 0.16 ppb.

- California DFR Summary, July 8, 2003

  California DFR has provided EPA with a summary of historical surface water monitoring data in their SURF database through July, 2000. The total amount of diuron used in California from 1990 to 1998 was just over ten million pounds. Diuron was the most frequently detected (57.2% or 350 of 612 samples) of the 146 chemicals in the SURF database. The median concentration was 0.281 ppb, the 75th percentile was 0.719 ppb, and the 95th percentile was 3.6 ppb.

- Texas Playa Lakes Study

  A study on the occurrence of cotton herbicides and insecticides in the Playa Lakes area of the high plains of western Texas was evaluated. Diuron and metabolites were found in 71% of the samples collected from 32 lakes at a mean concentration of 2.7 ppb. This study did not have sufficient frequency of sampling or a long enough sampling period to be used for regulatory purposes. In addition, the study has limited use in a National assessment because western Texas is not expected to be one of the most vulnerable use areas for runoff, the method of contamination expected with diuron. However, because samples were taken within 2 days of application, the results provide an indication of concentrations that could occur in drinking water in that area.

b. Ground Water

In the absence of monitoring data, the Screening Concentration in Ground Water (SCI-GROW) model, which is a Tier I assessment, was used to estimate potential ground water concentrations. SCI-GROW estimates likely groundwater concentrations if the pesticide is used at the maximum allowable rate in areas where groundwater is exceptionally vulnerable to contamination. This assessment represents a conservative estimate and in most cases, a large majority of the use area will have groundwater that is less vulnerable to contamination than the areas used to derive the SCIGROW estimate. Application of diuron to citrus in Florida was modeled. These scenarios represent high application rates and areas vulnerable to ground water contamination. The modeled estimates indicate that ground water concentrations of diuron and its metabolites are below the chronic DWLOC.

For more information on drinking water risks and the DWLOC calculations, see the Water Exposure section of the July 9, 2003, Human Health Risk Assessment, the March 11, 2002 memorandum entitled, “Drinking Water Reassessment for Diuron and its Degradates” and the August 5, 2003 memorandum entitled, "Surface Water Monitoring Data for Diuron."

c. Drinking Water Risk Estimates

To determine the maximum allowable contribution of pesticide residues in water, EPA first looks at how much of the overall allowable risk is contributed by food and then determines a "drinking water level of comparison" (DWLOC) to determine whether modeled or monitoring levels exceed this level. The Agency uses the DWLOC as a surrogate to capture risk associated with exposure from pesticides in drinking water. The DWLOC is the maximum concentration in drinking water which, when considered together with dietary exposure, does not exceed a level of concern.

The results of the Agency's drinking water analysis are summarized in Table 8. Details of the drinking water analysis are found in the Human Health Risk Assessment for Diuron, dated September 8, 2003.

Table 8. Estimated Environmental Concentrations and Chronic DWLOCs for Diuron and its Degradates

	Estimated Environmental Concentrations in Surface and Ground Water for Diuron and its Degradates from Diuron Use on Citrus		
	Estimated Environmental Concentrations (µg/L)		
	Diuron	**MCPDMU**	**DWLOC[4]**
Surface Water Monitoring Data	<1[1,2]	<1[1,3]	28
Groundwater (peak and long-term average)	9.1[2]	0.59[3]	

1 Increased 20% to account for degradates, as indicated by modeling work.
2 Includes modeled values for the following degradates: DCPMU; DCPU; and 3,4-DCA.
3 Based on modeling, using 6.4 lbs ai/A application rate for citrus.
4 For the most sensitive subpopulation, children 1 - 6 years.

Cancer Drinking Water Risk

For diuron potential cancer risk, no DWLOC has been calculated. Food alone shows a slight exceedance for cancer risk (1.68×10^{-6}) based on field trial data using maximum application rates. These estimates can be refined with additional residue and processing data. To better characterize both potential cancer risks from surface water, EPA has used monitoring data from Florida, an area of high diuron use, and other states. These data indicate detections generally one to two orders of magnitude lower than modeled estimates for diuron (parent compound). Based on this new data, the Agency has concluded that cancer risk from diuron in drinking water is not a concern. The monitoring data for Florida can be found on the following website: www.sfwmd.gov/curre/pest/pestindex.htm. For more information on cancer risks from drinking water, please see the Aggregate Risk Section below.

MCPDMU Risk

For the degradate MCPDMU, the Agency calculated the EEC using drinking water monitoring data. The monitoring data indicates the EEC for diuron is <1 ppb, including all of the degradates. Although the water monitoring data do not include data on the degradates of diuron, the Agency has increased the EECs by 20 percent, as indicated by conservative modeling, to account for the degradates. The < 1ppb calculation includes the estimation for the degradates. The < 1 ppb EEC for MCPDMU is below the cancer DWLOC and is not of concern. In addition, environmental fate data are required to confirm estimates of the concentrations and persistence of MCPDMU in water.

As a comparison, the Agency used modeling to calculate the EECs with the revised maximum application rate (6.4 lb ai/A) for citrus. The modeled EEC for MCPDMU is 6.94 ppb, consistent with the monitoring results.

3. Diuron: Residential Exposure and Risk

There are two potential sources of exposure to diuron in a residential setting - as an algaecide in ponds and aquariums, and as a preservative or a mildewcide in paints. Exposure from the dermal and inhalation routes are combined for each residential use.

a. Toxicity

Table 9 details the results of the hazard assessment for the non dietary risk assessment for diuron.

Table 9. Toxicity Endpoints Selected for Assessing Residential Risks for Diuron

Route / Duration	NOAEL (mg/ kg/day)	Effect	Study	Uncertainty Factors and Safety Factors
Short-term Incidental Oral (1 to 30 days)	10	Decreased body weight and food consumption	Developmental toxicity study in rabbits	Interspecies: 10x Intraspecies: 10x FQPA: 1x
Intermediate-term Incidental Oral (one month to six months)	1.0	Altered hematological parameters observed at six months.	Chronic toxicity/carcinogenicity study in rats	Interspecies: 10x Intraspecies: 10x FQPA: 1x
Short- and intermediate-term Dermal	No systemic toxicity following repeated dermal dosing at 1200 mg/kg/day was seen in the dermal toxicity study. Also, there is no developmental concern. No hazard was identified and no quantitative assessment is required.			
Long-term Dermal[a] (greater than six months)	1.0 (LOAEL)	Evidence of hemolytic anemia and compensatory hematopoiesis.	Chronic toxicity/carcinogenicity study in rats	Interspecies: 10x Intraspecies: 10x FQPA: 1x Use of LOAEL instead of a NOAEL: 3x
Short-term Inhalation[b]	10	Decreased body weight and food consumption	Developmental toxicity study in rabbits	Interspecies: 10x Intraspecies: 10x FQPA: 1x
Intermediate-term Inhalation[b]	1.0	Altered hematological parameters observed at six months	Chronic toxicity/carcinogenicity study in rats	Interspecies: 10x Intraspecies: 10x FQPA: 1x
Long-term Inhalation[b]	1.0 (LOAEL)	Evidence of hemolytic anemia and compensatory hematopoiesis	Chronic toxicity/carcinogenicity study in rats	Interspecies: 10x Intraspecies: 10x FQPA: 1x Use of a LOAEL instead of a NOAEL: 3x
Cancer	Known/ likely human carcinogen $Q_1^* = 1.91 \times 10^{-2}$	Urinary bladder carcinoma in both sexes of the Wistar rat, kidney carcinomas in the male rat (a rare tumor), and mammary gland carcinomas in the female NMRI mouse	Carcinogenicity study in rats and mice	

a An oral endpoint was used for dermal exposure: dermal absorption factor of 4% of oral exposure shall be used.
b An oral endpoint was used for inhalation exposure: inhalation exposure assumed equivalent to oral exposure.

Similar to dietary cancer risk, potential residential cancer risk is calculated by using the average exposure over a 70-year lifetime. The lifetime exposure value is typically combined with a linear low-dose (Q_1^*) approach to determine the lifetime (cancer) risk estimate.

b. Residential Handler Risk

(1) Exposure Scenarios, Data, & Assumptions

There are potential residential exposures from activities associated with pond and aquarium use and paint and stain use. Though there are existing labels for applications of granular formulations of diuron to turf, most are limited to industrial and non-crop uses. Others products are either pending cancellation by the registrant or the registrant has agreed to place language specifically eliminating residential uses on the label. Since residential turf uses are being canceled for diuron, a residential assessment for turf was not conducted.

The algaecide products are formulated as tablets/blocks and as a liquid. There are no exposure data for the use of the algaecide tablets/blocks. Since the products are formulated as tablets/blocks and dissolve in less than 5 minutes, minimal exposure is expected and was not quantified. The liquid is used at a rate of one teaspoon (5 ml) for every 10 gallons of aquarium or pond water, once a month or when algae growth reappears. Residential exposure may result from measuring the liquid and pouring the liquid into the aquarium or pond. Exposure is expected to be short-term (1 to 30 days). These risks are not of concern. For more information, see "Diuron: the Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)," dated September 8, 2003.

Residential painters using paints and stains were assumed to use airless sprayers and paint brushes. Exposure is expected to be short-term (1 to 30 days). For homeowners, the airless sprayer is assumed to be used for outdoor applications only. For indoor applications, EPA assumed that painting would be restricted to small rooms such as bathrooms (high potential for moisture) where an airless sprayer is unlikely to be used. These risks are not of concern. The following three residential handler scenarios were evaluated:

(1) Loading ready to use liquids;

(2) Applying paints or stains with a paintbrush; and

(3) Applying paints with an airless sprayer.

The following assumptions were used in the non-cancer exposure calculations:

- Average body weight of an adult handler is 70 kg.
- The average residential aquarium is assumed to be 50 gallons and the average residential pond is assumed to be 1,000 gallons. The No More Algae liquid label also states that the maximum residential pond that can be treated is 3,000 gallons, so this volume was assessed as a high end, maximum exposure value.
- The amount of paint used per day for residential handlers is 15 gallons for airless

sprayer, two gallons for paintbrush applying paint and five gallons for paintbrush applying stain. For homeowners, the airless sprayer is assumed to be used for outdoor applications only. Homeowner use of diuron treated paint indoors is restricted to small rooms such as bathrooms, laundry rooms, etc. where the use of an airless sprayer is unlikely to occur.

- In addition to diuron's mildewcide use in paints and stains, it is also used in plaster, stuccos, sealants, caulking, and fillers. Unit exposure data only exists for the use of paints/stains with airless sprayer and paintbrush. These exposure scenarios are assumed to have a higher exposure than use of diuron in plaster, stucco, sealants, caulking and fillers, since less material would be applied in a day. Therefore, the paint/stain assessment will also be considered an estimate of the exposure resulting from the use of diuron in plaster, stucco, sealants, caulking, and fillers.

- Application rates - The concentration of diuron in the paint, caulking, and other products is 0.2 to 2.5 percent. The maximum amount of diuron per gallon of paint is 0.0532 lbs ai/gallon paint.

- Exposure frequency - The secondary residential handlers are expected to be of a short-term duration (less than 30 days).

The following assumptions and factors were used in addition to previously stated residential non-cancer handler assumptions in order to complete this cancer risk assessment:

- The average lifetime is assumed to be 70 years.

- Exposure duration is assumed to be 50 years.

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- The number of exposures per year for the pond and aquarium uses are based on the label recommendations. The "No More Algae" liquid label states that "For regular maintenance, use once a month or as algae starts to reappear." Therefore, 12 exposures per year were assumed.

- Homeowners applying diuron treated paint are exposed two days per year. Since it would be unusual for homeowners to paint their houses every year with diuron treated paint, this is considered to be a high-end estimate.

- Homeowners are assumed to be wearing short-sleeved shirt and short pants and no personal protective equipment (PPE).

No chemical specific handler exposure data have been submitted to determine the extent of these exposures. Secondary residential handlers are assessed using an airless sprayer and a paint brush. The Pesticide Handler Exposure Database (PHED) was used to estimate

homeowner exposure while using diuron-treated paint. For comparative purposes, the Agency calculated homeowner exposure to diuron while using a paint brush and an airless sprayer using data submitted for another pesticide. These calculations indicate risks similar to those that were derived from using the PHED.

Although there is potential exposure during the application of the other treated materials (caulks and sealants), they are not included in this assessment because no data are available to assess these uses. There is also a potential for exposure from applying paint with a roller. However, it is the Agency's conclusion that the airless sprayer and paintbrush scenarios represent the high end exposures for diuron antimicrobial secondary handler uses.

(2) Residential Handler Risk Characterization

Summary of Non-Cancer Risk Concerns for Residential Handlers

The short term inhalation NOAEL of 10 mg/kg/day was used for all non-cancer exposures and had a target MOE of 100. The calculations of short-term inhalation risk from exposure to the liquid formulation of diuron indicate that inhalation MOEs are more than 100 for the all the assessed exposure scenarios and are not considered risks of concern. Although no data are available to assess exposures and risks from the block/tablet form of diuron, exposure from the block/tablet forms of diuron are expected to be less than exposure from the liquid formulation, and therefore are not a risk of concern. For more information, see "Diuron: the Revised HED Chapter of the Reregistration Eligibility Decision Document (RED)," dated September 8, 2003.

Residential Cancer Risk Characterization

The applicator assessment for paints and stains applied with a brush or an airless sprayer is based on a Q_1* of 1.91 x 10^{-2} $(mg/kg/day)^{-1}$, and an application rate of 0.053 lb ai per gallon. This is the maximum application rate. For a cancer risk assessment, typical rates would ordinarily be used but these were not available. The assessment also assumes two gallons for paints to five gallons for stains applied with a brush per day or fifteen gallons applied per day with an airless sprayer, 2 applications per year, 50 years of use over a 70 year lifetime, and a high-end dermal absorption factor of 4%. Usage information gathered subsequent to the risk assessment indicates that less than 1% of all paint contains diuron. Therefore, it is unlikely that a homeowner would only apply paint containing diuron two times per year for 50 years. The diuron cancer risk estimates are presented in Table 10 below.

Table 10. Diuron Cancer Exposure and Risk Estimates for Homeowner Pond/Aquarium, Paint and Stain Application

Exposure Scenario (Scenario #)	Use site	Application Rate	Amount Treated	Total Daily Dose[a]	Baseline Daily LADD[b,c]	Baseline Risk[d]
Mixer/Loader (12 days/year)						
(1) Loading Ready to Use Liquids	pond	0.0000074 lb ai per gallon	3000 Gallons per day	0.000037	8.7 E-7	1.7 E-8
	pond	0.0000074 lb ai per gallon	1000 Gallons per day	0.000012	2.9 E-7	5.5 E-9
	aquarium	0.0000074 lb ai per gallon	50 Gallons per day	0.00000062	1.5 E-8	3.0 E-10
Applicator (2 days/year)						
(2) Applying Paint/Stains with Paintbrush	Paint	0.0532 lb ai per gallon	2 Gallons per day	0.014	5.5 E-5	1.1 E-6
	Stains	0.0532 lb ai per gallon	5 Gallons per day	0.036	1.4 E-4	2.7 E-6
(3) Applying Paint with Airless Sprayer	Paint	0.0532 lb ai per gallon	15 Gallons per day	0.045	1.8 E-4	3.4 E-6

a Total Daily Dose (mg/kg/day) = Daily Dermal Dose (mg/kg/day) * Dermal Absorption (4%) + Daily Inhalation Dose (mg/kg/day). See Table 13 for daily dermal and inhalation doses.

b The number of exposures per year are based on the label recommendations. The No More Algae Liquid label states that " For regular maintenance, use once a month or as algae starts to reappear." Therefore, 12 exposures per year were assumed. Two exposure per year assumed for residential person painting their home.

c Lifetime average daily dose (LADD) (mg/kg/day) = Total Daily Dose (mg/kg/day) * (number of days of exposure per year / 365 days/year) * (50 years exposed / 70 years in a lifetime).

d Cancer risk = LADD (mg/kg/day) * Q1 (1.91E-2 mg/kg/day).

c. Residential Postapplication Risk Characterization

(1) Exposure Scenarios, Data, & Assumptions

Residential postapplication inhalation and dermal exposure is expected to occur from the use of diuron in ponds and aquariums and from the indoor use of paints and stains. The following residential postapplication scenarios were evaluated:

(1) Inhalation exposure from diuron use in ponds and aquariums;

(2) Dermal exposure from diuron use in ponds and aquariums;

(3) Inhalation exposure from the indoor use of diuron paints or stains; and

(4) Dermal exposure from the indoor use of diuron paints or stains.

Note that postapplication exposure to turf is no longer considered in the residential postapplication risk assessment. The registrants have agreed to prohibit turf treatment in residential areas.

The following assumptions were used:

- Typical homeowner clothing indoors is represented by short pants, short sleeve shirt, no gloves.
- The average body weight of 70 kg was used.
- Diuron products applied to ponds or aquariums is in tablet/block or a ready-to-use liquid form.
- Two tablet products were assessed, one product that requires using one tablet for every 10 gallons of aquarium or pond water and one product that requires using one tablet for every 250 gallons of pond water.
- Short-term exposure of one to 30 days for pond/aquarium treatment and for paint/stain use.

(2) Residential Postapplication Risk Characterization

Postapplication inhalation and dermal exposure resulting from the use of diuron in ponds and aquariums is expected to be minimal and not of concern. Diuron is applied to ponds/aquariums in the form of a liquid and an effervescent tablet. Due to the high dilution rate of the liquid in pond and aquarium water (0.0000074 lb ai per gallon of water), and the effervescent nature of the tablet (expected to dissolve in less than five minutes), postapplication exposure to diuron in pond and aquarium water is expected to be minimal. Furthermore, postapplication activities in and around ponds/aquariums treated with diuron are assumed to be infrequent.

Postapplication inhalation and dermal exposure resulting from the indoor use of diuron in paints is also expected to be minimal and not of concern. HED has conducted a screening-level inhalation assessment using the Multi-Chamber Concentration and Exposure Model (MCCEM). MCCEM uses air infiltration and interzonal air flow rates, together with user inputs for emission rates, decay rates, and outdoor concentrations to calculate time-varying indoor concentrations and associated indoor inhalation exposure due to product or material emissions in several zones or chambers within a residence. The results of this model, coupled with diuron's low vapor pressure (2×10^{-7} mm Hg at 30 °C), show minimal postapplication inhalation exposure. Furthermore, diuron-treated paint is only likely to be used in rooms where high humidity is expected (i.e. a bathroom), and would rarely be used in the entire house. It is unlikely that a homeowner would receive a significant amount of postapplication inhalation exposure from diuron-treated paint, as the very nature of its use is as a mildewcide, and any substantial loss of

the active ingredient from the paint would render the product ineffective.

4. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. For diuron, aggregate risk assessments were conducted for short-term (one to thirty days), and chronic (several months to lifetime) exposures. The aggregate risk assessments for chronic exposures include a non-cancer and a cancer risk assessment. No acute or intermediate-term aggregate risks were assessed because there was no systemic toxicity seen in the acute oral or 21-day dermal toxicity study.

a. Acute Aggregate Risk

No adverse effects attributed to a single exposure to diuron were identified in any available studies. Therefore, no acute dietary risk assessment was warranted.

b. Short-Term Aggregate Risk

When potential food and residential inhalation exposures are combined they result in aggregate short-term MOEs of 1043 and 1045 for adult males and females, respectively, which are not of concern. Based on labeled uses, no intermediate- or long-term residential handler, or substantial postapplication exposures of any duration, are expected.

Aggregate short-term risk estimates for diuron and its metabolites hydrolyzable to 3,4-DCA would combine exposures from food (average), water, and residential inhalation only. Estimates of allowable levels of diuron in drinking water were calculated using DWLOCs. The Agency determined that it was unlikely that more than one of the residential handler activities would occur concurrently during a short-term time period. Therefore, the Agency took the protective approach of including the exposures from the activity which could potentially result in the most exposure to the homeowner, applying paint with an airless sprayer, in the aggregate assessment. As noted previously, residential exposures are calculated using short-sleeved shirt and short pants (no personal protective equipment, no engineering controls).

An MOE was calculated to estimate the short-term aggregate risk, combining food and inhalation exposures, and using a NOAEL of 10 mg/kg/day. A UF of 100 (10x for interspecies extrapolation, 10x for intraspecies variability) and the 1x FQPA safety factor for diuron were applied to the assessment; therefore, an MOE of greater than 100 is not of concern. As shown in Table 11, the surface water and groundwater EECs are below the DWLOCs and are not of concern.

Table 11. Diuron Aggregate DWLOCs for Short-Term Exposures

Population Subgroup[1]	Aggregate Risk MOE [2] (food and residential)	Surface Water EEC [3] (ppb)	Ground Water EEC [3] (ppb)	Short-Term DWLOC [4] (ppb)
Adult Males	1043	104	9.1	3153
Adult Females	1045			2700

[1] Only adults are included in aggregate risk assessment; it is assumed that only adults will apply paint
[2] Aggregate MOE = [NOAEL ÷ (Avg Food Exposure + Residential Exposure)]
[3] The crop producing the highest level was used to assess exposure to diuron, DCPMU, DCPU, 3,4-DCA, total.
[4] DWLOC(µg/L) = [maximum water exposure (mg/kg/day) x body weight (kg)] / [water consumption (L) x 10^{-3} mg/µg]

c. Chronic (Non-Cancer) Aggregate Risk

Aggregate chronic (noncancer) risk estimates include the contribution of exposure from dietary sources (food + water) and residential sources. However, based on the labeled uses, no long-term or chronic residential exposures are expected. Chronic risk estimates from exposures to food, associated with the use of diuron do not exceed the Agency's level of concern for the most highly exposed population subgroup, children ages 1-6 years of age. The chronic dietary (food only) risk estimate for children ages 1-6 years of age was < 7% of the chronic PAD.

The original Tier 2 drinking water assessment was based on the PRZM/EXAMS model and identified chronic drinking water concerns. Since that time, the registrant has submitted an analysis of surface water supplies identified using Geographic Information Systems information from Florida, coupled with water monitoring data. The submitted data, combined with additional monitoring data that was subsequently identified, was reviewed and determined to have enough samples and be of sufficient quality to allow the Agency to refine the drinking water analysis. The revised chronic EEC is <1 ppb. Conservative models were used to determine that the diuron degradates would add an additional 20 percent to the concentration of the parent compound. The <1 ppb estimation includes the estimation for the degradates. Based on this new data, the Agency has concluded that chronic risk of diuron in drinking water is not a concern. For more information, please see the document titled "Environmental Risk Assessment for the Reregistration of Diuron," dated August 27, 2001. Table 12 presents the DWLOCs for various subpopulations.

Table 12 . DWLOCs for Chronic Non-Cancer Aggregate Dietary Exposure

Population Subgroup	Surface Water EECs (ppb)	Chronic DWLOC (ppb)
Non-Cancer		
U.S. Population	1	102
Females (13-50 years)		88
Infants (< 1 Year)		29
Children (1-6 years)		28

d. Cancer Aggregate Risk

The cancer aggregate risk assessment includes chronic dietary exposures from residues in food and water and a consideration of potential exposures from the residential uses of a chemical. In the case of diuron, separate cancer risk assessments have been conducted for the parent diuron and for its water metabolite, MCPDMU. EPA considers separate cancer assessments to be warranted because the target organs and Q_1* are different for parent and metabolite. The MCPDMU assessment relies on toxicity data from monuron, a structurally similar molecule that was formerly a registered pesticide. Like chronic dietary risk, potential cancer risk is calculated by using average consumption values for food and average residue values for those foods over a 70-year lifetime. The chronic exposure value is typically combined with a linear low-dose (Q_1*) approach to determine the lifetime (cancer) risk estimate.

Aggregate Cancer Risk from Diuron

Although estimated exposure to diuron residues in food alone results in a cancer risk estimate of 1.68×10^{-6} for the general population, the Agency believes that this estimate is not of concern based on several protective assumptions in the assessment. The estimates of exposure from food are based largely on field trial data conducted at the maximum application rates, with adjustments only for percent crop treated and some processing data. Further, even though PDP monitoring data show no detectable residues of diuron parent in any food commodity, EPA has made the protective assumption that all diuron converts to metabolites and has determined that these metabolite residues are as toxic as the parent compound. Drinking water monitoring data for several states with high usage of diuron, indicate average detections in the 0.05-0.28 ppb range. These levels, if sustained over a lifetime of exposure would result in risk estimates in the 1×10^{-6} range. Thus, combined food and drinking water risks would be $< 3 \times 10^{-6}$.

The residential uses of diuron result in only short-term exposures, generally less than 7 days per year, therefore the diuron cancer assessment based on Residential SOP provides a very conservative estimate of potential cancer risk. The assessment assumes an upper bound dermal absorption factor, even though no dermal toxicity was observed in a 28-day rabbit dermal toxicity study. Further, EPA has assumed 100% absorption by the inhalation route. Given the low vapor pressure of diuron, 2 x 10^{-7}mm Hg @ 30 C, absorption by the inhalation route is likely to be low. Finally, because of the low percent of paint containing diuron (<1%), lifetime exposure to home applicators of diuron-containing products is likely to be negligible.

Aggregate Risk from MCPDMU

For the MCPDMU aggregate assessment, EPA considered the potential contributions from drinking water and consumption of catfish. Because MCPDMU is only formed in water, these are the only potential sources of exposure to MCPDMU. Based on modeled estimates, the EEC for MCPDMU is 6.94 ppb, and represents a slight exceedance of the cancer DWLOC of 2 ppb. However, as mentioned in the Dietary Risk from Drinking Water Section, drinking water monitoring data was used to estimate the EECs of diuron and its degradates in drinking water. The monitoring data indicates the EEC for diuron is <1 ppb, including the degradates. Although the water monitoring data do not include data on the degradates of diuron, the Agency has increased the EECs by 20 percent, as suggested by modeling, to account for the degradates. In addition, environmental fate data are required to confirm estimates of the concentrations and persistence of MCPDMU in water.

Table 13. Summary of Cancer DWLOC Calculations for MCPDMU

Population Subgroup	Surface Water EECs (ppb)	Ground Water EECs (ppb)	$DWLOC_{cancer}$ (ppb)
U.S. Population	< 1*	1.4	2.0

* For comparative purposes, the modeled estimate for the surface water EEC is 6.94 ppb.

5. Occupational Risk

Occupational workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of diuron include: workers in right-of-way areas or industrial sites, workers in agricultural environments, workers applying paints or stains, workers in ornamental fish and catfish production and workers applying diuron to ornamental plants and trees in nurseries. Non-cancer risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL). In the case of diuron, MOEs greater than 100 do not exceed the Agency's level of concern. When evaluating cancer risks for the occupational population, EPA closely examines risks in the $1x10^{-4}$ to $1x10^{-6}$ range and seeks cost effective ways to reduce occupational cancer risks to the greatest extent feasible, preferably $1x10^{-6}$ or less.

Calculations of noncancer risk based on inhalation exposure indicate that the inhalation margins of exposure (MOEs) are more than 100 with PPE or engineering controls for all of the short-term occupational exposure scenarios except applying sprays with a high pressure handwand. Sixteen of the 31 occupational scenarios were identified as having intermediate-term durations of exposure. Of these, none have a non-cancer risk of concern for intermediate-term inhalation exposure with PPE or engineering controls. A noncancer postapplication risk assessment was not conducted, since no systemic toxicity by the dermal route is expected for the short- or intermediate-term durations. Postapplication cancer risks for private growers were calculated at both the typical application rate and the maximum application rate for each crop grouping.

Occupational risk assessments were conducted for the use of diuron as a mildewcide in paint. Four occupational handler scenarios were identified for the use of diuron in paint and are expected to be of short- and intermediate-term exposure duration. The calculations of short- and intermediate-term inhalation risk from the use of diuron in paint indicate that MOEs are more than 100 at the assessed level of mitigation for all the exposure scenarios, except applying paints with an airless sprayer (indoors). At the assessed level of mitigation, all paint scenarios have potential cancer risks between 1×10^{-4} and 1×10^{-6}. Occupational postapplication exposures to paint containing diuron may occur in industrial settings around open vats used in paint processing. Inhalation and dermal exposures may also occur while maintaining industrial equipment. No postapplication exposure data have been submitted to determine the extent of postapplication exposures in the industrial settings. Nonetheless, inhalation exposures are expected to be minimal because of the low vapor pressure of diuron (2×10^{-7} mm Hg at 30 °C) and aerosol formation is not expected. Dermal postapplication exposures are expected to be lower than when handling/loading the formulated product. Therefore, postapplication exposures in the industrial settings are expected to be minimal and not of concern.

Occupational risk assessments were also conducted for the use of diuron as an algaecide in commercial fish ponds. Four short-term occupational handler scenarios were identified for the use of diuron in commercial fish production and the inhalation MOEs from all four of the commercial fish production scenarios were greater than 100 at the baseline level of mitigation and are not of concern. With maximum mitigation measures (engineering control level), all four scenarios have estimated cancer risks of less than 1×10^{-6} and are not of concern. Occupational postapplication exposure to diuron in treated fish production ponds is not likely to result in a risk of concern based on the extremely high dilution rate

a. Toxicity

The acute toxicity profiles for diuron is listed previously in Table 3. Table 14 details the toxicity endpoints used in the occupational risk assessment for diuron.

Table 14: Toxicity Endpoints for Diuron Risk Assessment

Route / Duration	NOAEL (mg/ kg/day)	Effect	Study	Uncertainty Factors and Safety Factors
Short- and intermediate-term Dermal	No systemic toxicity following repeated dermal dosing at 1200 mg/kg/day was seen in the dermal toxicity study. Also, there is no developmental concern. No hazard was identified and no quantitative assessment is required.			
Long-term Dermal[a] (greater than six months)	1.0 (LOAEL)	Evidence of hemolytic anemia and compensatory hematopoiesis.	Chronic toxicity/carcinogenicity study in rats	Interspecies: 10x Intraspecies: 10x FQPA: 1x Use of LOAEL instead of a NOAEL: 3x
Short-term Inhalation[b]	10	Decreased body weight and food consumption	Developmental toxicity study in rabbits	Interspecies: 10x Intraspecies: 10x FQPA: 1x
Intermediate-term Inhalation[b]	1.0	Altered hematological parameters observed at six months	Chronic toxicity/carcinogenicity study in rats	Interspecies: 10x Intraspecies: 10x FQPA: 1x
Long-term Inhalation[b]	1.0 (LOAEL)	Evidence of hemolytic anemia and compensatory hematopoiesis	Chronic toxicity/carcinogenicity study in rats	Interspecies: 10x Intraspecies: 10x FQPA: 1x Use of a LOAEL instead of a NOAEL: 3x
Cancer	Known/likely human carcinogen $Q_1^* = 1.91 \times 10^{-2}$	Urinary bladder carcinoma in both sexes of the Wistar rat, kidney carcinomas in the male rat (a rare tumor), and mammary gland carcinomas in the female NMRI mouse	Carcinogenicity study in rats and mice	

a An oral endpoint was used for dermal exposure: dermal absorption factor of 4% of oral exposure shall be used.
b An oral endpoint was used for inhalation exposure: inhalation exposure assumed equivalent to oral exposure.

b. Agricultural Handler Exposure

Based on the registered use patterns, EPA has identified 31major exposure scenarios for which there is potential occupational handler exposure during mixing, loading, and applying products containing diuron. These scenarios are as follows:

(1a) mixing/loading liquid formulations for aerial application;
(1b) mixing/loading liquid formulations for chemigation;
(1c) mixing/loading liquid formulations for groundboom application;
(1d) mixing/loading liquid formulations for rights-of-way sprayers;

(1e) mixing/loading liquid formulations for high-pressure hand wand;
(2a) mixing/loading dry flowables for aerial application;
(2b) mixing/loading dry flowables for chemigation;
(2c) mixing/loading dry flowables for groundboom application;
(2d) mixing/loading dry flowables for rights-of-way spray application;
(2e) mixing/loading dry flowables for high-pressure hand wand;
(3a) mixing/loading wettable powders for aerial application;
(3b) mixing/loading wettable powders for chemigation;
(3c) mixing/loading wettable powders for groundboom application;
(3d) mixing/loading wettable powders for rights-of-way spray application;
(3e) mixing/loading wettable powders for high-pressure hand wand;
(4) loading granulars for tractor-drawn spreaders;
(5) applying sprays for aerial application;
(6) applying sprays for groundboom application;
(7) applying sprays with a rights-of-way sprayer;
(8) applying sprays with a high-pressure hand wand;
(9) applying granulars for a tractor-drawn spreader;
(10) applying granulars with a spoon;
(11) applying granulars for hand application;
(12) flagging aerial spray applications;
(13) mixing/loading/applying liquids with a low-pressure hand wand;
(14) mixing/loading/applying liquids with a backpack sprayer;
(15) mixing/loading/applying wettable powders with a low-pressure hand wand;
(16) loading/applying granulars with a pump feed backpack spreader;
(17) loading/applying gravity feed backpack spreader;
(18) loading/applying granulars for a belly grinder application; and
(19) loading/applying granulars with a push-type spreader.

Since granulars are only used on non-crop/utility areas, aerial application of granulars and flaggers supporting aerial granular applications were not assessed.

For agricultural handlers, the estimated exposures initially are assessed assuming handlers are using baseline attire (i.e., long-sleeve shirt, long pants, shoes, and socks). If risk estimates exceed the level of concern for a given scenario with baseline attire, then exposures are assessed with the addition of personal protective equipment (i.e., chemical-resistant gloves, double-layer body protection, and/or a respirator) as required. In general, the Agency uses the least PPE necessary to achieve risk estimates that do not exceed the level of concern. If the risk estimates exceed the Agency's level of concern (i.e., if MOE < 100) for a given scenario even with the addition of PPE, then the risks are assessed with the use of engineering controls (i.e., closed system mixing/loading and enclosed cabs or cockpits for applying and flagging).

Agricultural Handler Data Sources

The analyses for the diuron risk assessment were performed using the following sources of data:

- Outdoor Residential Exposure Task Force (ORETF). The task force recently submitted proprietary data to the Agency on hose-end sprayers, push-type granular spreaders, and handgun sprayers (MRID # 44972201). The ORETF data were used in this assessment in place of PHED data for the "loading/applying granulars using a push-type spreader" scenario.

- Available data were used to assess exposures and risks to occupational handlers loading and applying granulars using a scoop and bucket, these estimates are used as range-finding estimates for the applications made with a spoon or by hand.

- Pesticide Handlers Exposure Database (PHED). PHED was designed by a task force of representatives from the US EPA, Health Canada, the California Department of Pesticide Regulation, and member companies of the American Crop Protection Association, now known as Crop Life America. It is a software system consisting of two parts - a database of measured exposure values for workers involved in the handling of pesticides under actual field conditions and a set of computer algorithms used to subset and statistically summarize the selected data. Currently, the database contains values for over 1,700 monitored individuals (i.e., replicates). The quality of the data and exposure factors represents the best sources of data currently available to the Agency for completing these kinds of assessments.

Agricultural Handler Exposure Assumptions

The following assumptions and factors were used in order to complete the exposure and risk assessments for occupational handlers/applicators:

Calculations were completed for a range of maximum application rates for crops specified on current diuron labels and in the Label Usage and Information System (LUIS) report. These rates were assessed in order to bracket risk levels associated with the various use patterns.

- Average body weight of an adult handler was assumed to be 70 kg.

- Daily (8-hour workday) acres and volumes (as appropriate) to be treated in each scenario include:

- Exposures were estimated for handlers using 1,200 and 350 acres per day for aerial equipment. The use of 1,200 acres treated in one day by either the mixer/loader or the applicator is considered a reasonable high-end estimate, because these crops are high acreage field crops. This maximum acres treated aerially per day is based on published scientific literature, surveys, knowledge of agricultural practices, and calculated acreage estimates.

- 350 acres for aerial applications to all agricultural crops, except for cotton, and alfalfa;
- 350 acres for flaggers supporting aerial applications;
- For groundboom equipment use on high acreage crops such as cotton, small grains (wheat, barley, and oats), alfalfa and corn, a range of 200 acres per day to 80 acres per day was used. For all other crops, 80 acres was used;
- 1000 gallons for high-pressure hand wands and rights-of-way sprayers;
- 350 acres for chemigation;
- 40 gallons for low-pressure hand wands and backpack sprayers;
- 80 acres for tractor-drawn spreader;
- 5 acres for a push-type spreader and backpack spreaders, 1 acre for a belly-grinder and 100 square feet for granular hand and spoon application; and
- 50 gallons for airless sprayer and 5 gallons for paintbrush.
- If scenario-specific data are lacking, the Agency will calculate unit exposure values using generic protection factors that are applied to represent the use of personal protective equipment (PPE) and engineering controls. This assessment used an 80 percent protection factor applied to baseline inhalation unit exposure values to represent use of a dust/mist respirator (currently required on some labels).
- The duration of exposure for handlers of diuron is assumed to be mostly short-term (one day to one month). Intermediate-term exposure (one month to several months) for handlers is possible for large field crops, including corn, wheat, oats and cotton, because of their long planting seasons. Since only aerial and chemigation equipment, and groundboom sprayers are used to treat these crops, only the scenarios with this equipment and the supporting flagger scenario were assessed for the intermediate term. Only for the highest application rate for the four crops, cotton at 2.2 lbs ai/acre, was assessed for the intermediate term.
- Rights-of-way sprayer scenarios for utility and industrial areas are assumed to be intermediate-term duration, because utility workers could possibly treat rights-of-way areas (roadsides, railroads, etc) all summer long.

c. Agricultural Handler Non-Cancer Risk

The duration of exposure is expected to be short-, and intermediate-term for occupational handlers. The exposure duration for short-term assessments is 1 to 30 days, while intermediate-

term durations are 1 to 6 months. Non-cancer risk estimates are expressed in terms of the Margin of Exposure (MOE). For occupationally exposed workers, MOEs greater than or equal to 100 and are not of concern. A summary of Occupational Handler Non-Cancer Risks are shown in Table 15.

Table 15. Diuron: Summary of Occupational Handler Non-Cancer Risks

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Inhalation MOEs		Necessary Level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	
Occupational Mixer/Loader Estimates for MOE 100 or Highest Achievable MOE						
(1a) Mixing/ Loading Liquids for Aerial Application	Sugarcane	350 acres/day	6 lb ai/acre	280	-	Baseline
	Alfalfa	1200 acres/day	3.2 lb ai/acre	150	-	Baseline
	Cotton	350 acres/day	2.2 lb ai/acre	-	380	Minimum
	Cotton	1200 acres/day	2.2 lb ai/acre	-	110	Minimum
(1b) Mixing/ Loading Liquids for Chemigation Application	Sugarcane	350 acres/day	6 lb ai/acre	280	-	Baseline
	Cotton	350 acres/day	2.2 lb ai/acre	-	380	Minimum
(1c) Mixing/ Loading Liquids for Groundboom Application	Grapes	80 acres/day	9.6 lb ai/acre	760	-	Baseline
	Alfalfa	200 acres/day	3.2 lb ai/acre	910	-	Baseline
	Cotton	80 acres/day	2.2 lb ai/acre	-	330	Baseline
	Cotton	200 acres/day	2.2 lb ai/acre	-	130	Baseline
(1d) Mixing/ Loading Liquids for Rights-of-Way Application	Grapes	1000 gallons/day	0.19 lb ai/gallon	3000	-	Baseline
	Utility/industrial areas	1000 gallons/day	0.9 lb ai/gallon	650	-	Baseline
	Utility/industrial areas	1000 gallons/day	0.9 lb ai/gallon	-	320	Minimum
(1e) Mixing/Loading Liquids for High-Pressure Handwand Application	Grapes	1000 gallons/day	0.19 lb ai/gallon	3000	Not Applicable	Baseline
	Utility/industrial areas	1000 gallons/day	0.9 lb ai/gallon	650	Not Applicable	Baseline
(2a) Mixing/Loading Dry Flowables for Aerial Application	Sugarcane	350 acres/day	6.4 lb ai/acre	410	-	Baseline
	Alfalfa	1200 acres/day	3.2 lb ai/acre	240	-	Baseline
	Cotton	350 acres/day	2.2 lb ai/acre	-	120	Baseline
		1200 acres/day		-	180	Minimum

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Inhalation MOEs		Necessary Level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	
(2b) Mixing/Loading Dry Flowables for Chemigation Application	Sugarcane	350 acres/day	6.4 lb ai/acre	410	-	Baseline
	Cotton	350 acres/day	2.2 lb ai/acre	-	120	Baseline
(2c) Mixing/Loading Dry Flowables for Groundboom Application	Grapes	80 acres/day	9.6 lb ai/acre	1200	-	Baseline
	Alfalfa	1200 acres/day	3.2 lb ai/acre	1400	-	Baseline
	Cotton	80 acres/day	2.2 lb ai/acre	-	520	Baseline
		1200 acres/day		-	210	Baseline
(2d) Mixing/Loading Dry Flowables for Rights-of-Way Sprayer Application	Grapes	1000 gallons/day	0.19 lb ai/gallon	4700	-	Baseline
	Utility/Industrial Areas	1000 gallons/day	0.96 lb ai/gallon	950	-	Baseline
				-	490	Minimum
(2e) Mixing/Loading Dry Flowables for High-Pressure Handwand Application	Grapes	1000 gallons/day	0.19 lb ai/gallon	4700	-	Baseline
	Utility/Industrial Areas	1000 gallons/day	0.96 lb ai/gallon	950	-	Baseline

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Inhalation MOEs		Necessary Level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	
(3a) Mixing/Loading Wettable Powders for Aerial Application	Sugarcane	350 acres/day	6.4 lb ai/acre	1300	-	Engineering Controls
	Alfalfa	1200 acres/day	3.2 lb ai/acre	760	-	Engineering Controls
	Cotton	350 acres/day	2.2 lb ai/acre	-	380	Engineering Controls
	Cotton	1200 acres/day	2.2 lb ai/acre	-	110	Engineering Controls
(3b) Mixing/Loading Wettable Powders for Chemigation Application	Sugarcane	350 acres/day	6.4 lb ai/acre	1300	-	Engineering Controls
	Cotton	350 acres/day	2.2 lb ai/acre	-	380	Engineering Controls
(3c) Mixing/Loading Wettable Powders for Groundboom Application	Grapes	80 acres/day	9.6 lb ai/acre	110	-	Minimum
	Alfalfa	200 acres/day	3.2 lb ai/acre	130	-	Minimum
	Cotton	80 acres/day	2.2 lb ai/acre	-	1700	Engineering Controls
		200 acres/day	2.2 lb ai/acre	-	660	Engineering Controls
(3d) Mixing/Loading Wettable Powders for Rights-of-Way Sprayer Application	Utility/Industrial Areas	1000 gallons/day	0.96 lb ai/gallon	170	-	Maximum
	Grapes	1000 gallons/day	0.19 lb ai/gallon	420	-	Minimum
	Utility/Industrial Areas	1000 gallons/day	0.96 lb ai/gallon		300	Engineering Controls
(3e) Mixing/Loading Wettable Powders for High-Pressure Handwand Applications	Grapes	1000 gallons/day	0.19 lb ai/gallon	420	-	Minimum
	Utility/Industrial Areas		0.96 lb ai/gallon	170	-	Maximum
(4) Loading Granulars for Tractor-Drawn Spreaders Application	Utility/Industrial Areas	80 acres/day	87.1 lb ai/acre	300	Not Applicable	Minimum

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Inhalation MOEs		Necessary Level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	
Applicator						
(5) Applying Sprays for Aerial Application	Sugarcane	350 acres/day	6.4 lb ai/acre	4600	-	Engineering Controls
	Alfalfa	1200 acres/day	3.2 lb ai/acre	2700	-	Engineering Controls
	Cotton	350 acres/day	2.2 lb ai/acre	-	1300	Engineering Controls
		1200 acres/day	2.2 lb ai/acre	-	390	Engineering Controls
(6) Applying Sprays for Groundboom Application	Grapes	80 acres/day	9.6 lb ai/acre	1200	-	Baseline
	Alfalfa	200 acres/day	3.2 lb ai/acre	1500	-	Baseline
	Cotton	80 acres/day	2.2 lb ai/acre	-	540	Baseline
		200 acres/day	2.2 lb ai/acre	-	210	Baseline

	Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Inhalation MOEs		Necessary Level of PPE or Engineering Controls
					Short Term < 7 days	Intermediate Term < 30 days	
(7)	Applying Sprays for Rights-Of-Way	Grapes	1000 gallons/day	0.19 lb ai/gallon	930	-	Baseline
		Utility/Industrial Areas	1000 gallons/day	0.96 lb ai/gallon	190	-	Baseline
		Utility/Industrial Areas	1000 gallons/day	0.96 lb ai/gallon	-	190	Maximum
(8)	Applying Sprays for High-Pressure Handwand Application	Grapes	1000 gallons/day	0.19 lb ai/acre	230	Not Applicable	Minimum
		Utility/Industrial Areas	1000 gallons/day	0.96 lb ai/acre	92	Not Applicable	Maximum
(9)	Applying Granulars for Tractor-Drawn Spreaders Application	Utility/Industrial Areas	80 acres/day	87.1 lb ai/acre	420	Not Applicable	Minimum
(10)	Applying Granulars with a Spoon	Industrial Areas	100 sq. feet/day	87.1 lb ai/acre	78000	Not Applicable	Baseline
(11)	Applying Granulars for Hand Application	Industrial Areas	100 sq. feet/day	87.1 lb ai/acre	740	Not Applicable	Baseline
	Flagger						
(12)	Flagging for Sprays Application	Sugarcane	350 acres/day	6.4 lb ai/acre	890	-	Baseline
		Cotton	350 acres/day	2.2 lb ai/acre	-	260	Baseline
	Mixer/Loader/Applicator						
(13)	Mixing/Loading/Applying Liquids for Low Pressure Handwand Application	Industrial Areas	40 gallons/day	0.9 lb ai/gallon	650	Not Applicable	Baseline
(14)	Mixing/Loading/Applying Liquids for Backpack Sprayer Application	Industrial Areas	40 gallons/day	0.9 lb ai/gallon	650	Not Applicable	Baseline
(15)	Mixing/Loading/Applying Wettable Powders For Low Pressure Handwand Application	Industrial Areas	40 gallons/day	0.96 lb ai/gallon	170	Not Applicable	Maximum
(16)	Loading/Applying Granulars with a Pump Feed Granular Spreader	Industrial Areas	5 acres/day	87.1 lb ai/acre	380	Not Applicable	Baseline

Exposure Scenario	Crop Type or Target	Acres Treated or Gallons per Application	Application Rate (lbs a.i./A)	Inhalation MOEs		Necessary Level of PPE or Engineering Controls
				Short Term < 7 days	Intermediate Term < 30 days	
(17) Loading/Applying Granulars with Gravity Feed Backpack Spreader	Industrial Areas	5 acres/day	87.1 lb ai/acre	180	Not Applicable	Minimum
(18) Loading/Applying Granulars for Belly Grinder Application	Industrial Areas	1 acres/day	87.1 lb ai/acre	130	Not Applicable	Baseline
(19) Loading/Applying Granulars for Push-type Spreader Application	Industrial Areas	5 acres/day	87.1 lb ai/acre	210	Not Applicable	Baseline

a Crops named are index crops which are chosen to represent all other crops at or near that application rate for that use.
See the application rates listing in the use summary section of this document for further information on application rates used in this assessment.
b Application rates are based on the maximum application rates listed on the marketed diuron labels
c Amount handled per day from Science Advisory Council on Exposure's Policy #9.1
d Short-term MOE = Short-term NOAEL (mg/kg/day) / Daily Inhalation Dose (mg/kg/day)
e Baseline: long pants, long-sleeved shirt shoes and socks (no respirator)
f Minimum PPE: baseline plus dust mist respirator
g Maximum PPE: baseline plus organic vapor respirator
h Engineering controls: closed mixing/loading, enclosed cab, truck, or cockpit.
See the appendix, Tables A, B, C, and D for the inputs and dermal and inhalation does calculations.
- Scenario's calculated MOE exceeds the target MOE at the previous level of mitigation.
(MOE > 100), NF = Not feasible for this scenario (no available engineering controls).

d. Agricultural Handler Cancer Risk

Cancer risk estimates are presented as a probability of developing cancer. The cancer handler exposure scenarios are identical to those assessed in the noncancer handler assessment. However, it should be noted that the cancer assessment assumes 4 percent dermal absorption since exposures may be of duration longer than six months. A 28-day dermal toxicity study showed no adverse effects from diuron up to the limit dose of 1200 mg/kg/day. To assess cancer risk, a total daily dose, a lifetime daily dose and a total cancer risk are calculated. The total daily dose is calculated to include both dermal and inhalation exposure (dermal dose includes dermal absorption since an oral cancer endpoint was used) and used a Q_1*= 1.91 x 10^{-2} $(mg/kg/day)^{-1}$ in human equivalents. For occupational risks between 1x10^{-6} and 1x10^{-4}, the Agency will pursue risk mitigation where feasible and cost effective to reduce the risks to 1x10^{-6} or less.

The assessment assumed that the average lifetime is 70 years, exposure duration is 35 years, and that the exposures per year are: 10 days per year for the private grower and 30 days per year for a commercial applicator. Maximum application rates were used in the private grower assessment. Typical application rates were used in both the private grower and commercial applicator assessments. It was assumed that as the frequency of exposure increased, the probability of being exposed to a maximum application rate would decrease. Therefore, maximum application rates were not assessed for the commercial applicator. Tables 16 and 17 summarize the cancer risks associated with the handling of diuron for the baseline, maximum PPE and engineering control level of mitigation for commercial and private farmers, respectively. In general, the Agency is concerned when occupational cancer risk estimates exceed 1 x 10^{-4}. The Agency will seek ways to mitigate the risks, to the extent that it is practical and economically feasible, to lower the risks to 1 x 10^{-6} or less.

Five of the assessed scenarios have cancer risks greater than 1 x 10^{-4} at the highest feasible level of mitigation (private farmer/commercial applicator, typical/max rate) and are of concern. Twenty-six of the scenarios have cancer risks between 1 x 10^{-4} and 1 x 10^{-6} at the highest feasible level of mitigation (private farmer/commercial applicator, typical/max rate).

Table 16. Diuron: Summary of Occupational Handler Cancer Risks for Commercial Applicators

Diuron: Occupational Handler Cancer Risk Estimates Commercial Applicator/30 Exposures Per Year/Typical Application Rate			
Exposure Scenario	Cancer Risk Baseline (single layer)	Cancer Risk (double layer + gloves + half-face respirator w/P 95 filter)	Cancer Risk Engineering Controls
Mixer/Loader			
1a) Mixing/ Loading Liquids for Aerial Application	**1.8 E-3 - 3.9 E-3**	**1.3 E-5 - 2.7 E-5**	**6.7 E-6 - 1.4 E-5**
1b) Mixing/ Loading Liquids for Chemigation Application	**1.8 E-3**	**1.3 E-5**	**6.7 E-6**

Diuron: Occupational Handler Cancer Risk Estimates Commercial Applicator/30 Exposures Per Year/Typical Application Rate			
Exposure Scenario	Cancer Risk Baseline (single layer)	Cancer Risk (double layer + gloves + half-face respirator w/P 95 filter)	Cancer Risk Engineering Controls
1c) Mixing/ Loading Liquids for Groundboom Application	**4.2 E-4 - 6.6 E-4**	**2.9 E-6 - 4.5 E-6**	**1.5 E-6 - 2.4 E-6**
1d) Mixing/ Loading Liquids for Rights-of-Way Application	8.4 E-5 - 1.2 E-3	5.7 E-7 - 8.1 E-6	3.1 E-7 - 4.3 E-6
1e) Mixing/Loading Liquids for High-Pressure Handwand Application	8.4 E-5 - 1.2 E-3	5.7 E-7 - 8.1 E-6	3.1 E-7 - 4.3 E-6
2a) Mixing/Loading Dry Flowable for Aerial Application	5.4 E-5 - 1.2 E-4	3.1 E-5 - 6.6 E-5	1.1 E-6 - 2.3 E-6
2b) Mixing/Loading Dry Flowable for Chemigation Application	5.4 E-5	3.1 E-5	1.1 E-6
2c) Mixing/Loading Dry Flowable for Groundboom Application	1.2 E-5 - 1.9 E-5	7.0 E-6 - 1.1 E-5	2.4 E-7 - 3.8 E-7
2d) Mixing/Loading Dry Flowable for Rights-of-Way Sprayer Application	2.5 E-6 - 3.7 E-5	1.4 E-6 -2.1 E-5	4.8 E-8 - 7.2 E-7
2e) Mixing/Loading Dry Flowable for High-Pressure Handwand Application	2.5 E-6 - 3.7 E-5	1.4 E-6 - 2.1 E-5	4.8 E-8 - 7.2 E-7
3a) Mixing/ Loading Wettable Powders for Aerial Application	3.0 E-3 - 6.4 E-3	1.5 E-4 - 3.2 E-4	9.9 E-6 - 2.1 E-5
3b) Mixing /Loading of Wettable Powders for Chemigation Application	3.0 E-3	1.5 E-4	9.9 E-6
3c) Mixing/ Loading of Wettable Powders for Groundboom Application	6.9 E-4 - 1.1 E-3	3.4 E-5 - 5.3 E-5	2.3 E-6 - 3.5 E-6
3d) Mixing/ Loading Wettable Powders for Rights-of-Way Sprayer Application	1.4 E-4 - 2.1 E-3	6.8 E-6 - 1.0 E-4	4.5 E-7 - 6.8 E-6
3e) Mixing/Loading Wettable Powders for High-Pressure Handwand Application	1.4 E-4 - 2.1 E-3	6.8 E-6 - 1.0 E-4	4.5 E-7 -6.8 E-6
4) Loading Granular Formulation For Tractor-Drawn Spreader Application	1.6 E-4	2.4 E-5	3.2 E-6
Applicator			
5) Applying Sprays Aerially	See Engineering Controls	See Engineering Controls	4.2 E-6 - 9.0 E-6
6) Applying Sprays with Groundboom	4.7 E-6 - 7.3 E-6	1.8 E-6 - 2.9 E-6	8.7 E-7 - 1.4 E-6
7) Applying with a Rights-of-Way Sprayer	4.0 E-5 - 6.0 E-4	8.6 E-6 - 1.3 E-4	NF
8) Applying with a High-Pressure Handwand	1.1 E-4 - 1.6 E-3	1.6 E-5 - 2.4 E-4	NF
9) Applying Granular Formulations with a Tractor-Drawn Spreader	1.3 E-4	2.3 E-5	2.4 E-5
10) Applying Granulars with a Spoon	2.8 E-7	2.0 E-7	NF
11) Applying Granulars by Hand	7.4 E-5	3.7 E-5	NF

Diuron: Occupational Handler Cancer Risk Estimates Commercial Applicator/30 Exposures Per Year/Typical Application Rate			
Exposure Scenario	Cancer Risk Baseline (single layer)	Cancer Risk (double layer + gloves + half-face respirator w/P 95 filter)	Cancer Risk Engineering Controls
Flagger			
12) Flagging for Spray Application	1.2 E-5	6.8 E-6	2.5 E-7
Mixer/Loader/Applicator			
13) Mixing/ Loading/ Applying Liquids using Low Pressure Handwand	1.6 E-3	7.2 E-6	NF
14) Mixing/ Loading/ Applying Liquids using Backpack Sprayer	5.3 E-5	2.7 E-5	NF
15) Mixing/ Loading/ Applying Wettable Powder Formulations using Low Pressure Handwand	6.2 E-4	1.5 E-4	NF
16) Loading/ Applying Granulars using a Pump Feed Backpack Spreader	4.0 E-5	2.4 E-5	NF
17) Loading/ Applying Granulars using a Gravity Feed Backpack Spreader	3.3 E-4	1.6 E-4	NF
18) Loading/Applying Granulars with a Belly Grinder	4.5 E-4	3.1 E-4	NF
19) Loading/ Applying Granules using a Push-type Spreader	1.1 E-4	1.7 E-5	NF

NF = Not feasible

Table 17. Diuron: Summary of Occupational Handler Cancer Risks for Private Farmer

Diuron: Handler Risk Estimates for Cancer Private Farmer/10 Exposures Per Year						
Exposure Scenario	**Typical Application Rate**			**Maximum Application Rate**		
	Cancer Risk Baseline (i.e., single layer)	**Cancer Risk (double layer + gloves + respirator)**	**Cancer Risk Engineering Controls**	**Cancer Risk Baseline (i.e., single layer)**	**Cancer Risk (double layer + gloves + respirator)**	**Cancer Risk Engineering Controls**
Mixer / Loader						
1a) Mixing/ Loading Liquids for Aerial Application	6.1 E-4 - 1.3 E-3	4.2 E-6 - 9.0 E-6	2.2 E-6 - 4.8 E-6	9.2 E-4 - 1.7 E-3	6.3 E-6 - 1.2 E-5	6.1 E-6 - 3.4 E-6
1b) Mixing/ Loading Liquids for Chemigation Application	6.1 E-4	4.2 E-6	2.2 E-6	9.2 E-4	6.3 E-6	3.4 E-6
1c) Mixing/ Loading Liquids for Groundboom Application	1.4 E-4 - 2.2 E-4	9.6 E-7 - 1.5 E-6	5.1 E-7 - 8.0 E-7	2.8 E-4 - 3.4 E-4	1.9 E-6 - 2.3 E-6	1.0 E-6 - 1.2 E-6
1d) Mixing/ Loading Liquids for Rights-of-Way Application	2.8 E-5 - 3.9 E-4	1.9 E-7 - 2.7 E-6	1.0 E-7 - 1.4 E-6	8.4 E-5 - 3.9 E-4	5.7 E-7 - 2.7 E-6	3.1 E-7 - 1.4 E-6
1e) Mixing/Loading Liquids for High-Pressure Handwand Application	2.8 E-5 - 3.9 E-4	1.9 E-7 - 2.7 E-6	1.0 E-7 - 1.4 E-6	8.4 E-5 - 3.9 E-4	5.7 E-7 - 2.7 E-6	3.1 E-7 - 1.4 E-6
2a) Mixing/Loading Dry Flowable for Aerial Application	1.8 E-5 - 3.8 E-5	1.0 E-5 - 2.2 E-5	3.5 E-7 - 7.5 E-7	2.9 E-5 - 4.9 E-5	1.6 E-5 - 2.8 E-5	5.6 E-7 - 9.6 E-7
2b) Mixing/Loading Dry Flowable for Chemigation Application	1.8 E-5	1.0 E-5	3.5 E-7	2.9 E-5	1.6 E-5	5.6 E-7
2c) Mixing/Loading Dry Flowable for Groundboom Application	4.1 E-6 - 6.4 E-6	2.3 E-6 - 3.7 E-6	8.0 E-8 - 1.3 E-7	8.2 E-6 - 9.8 E-6	4.7 E-6 - 5.6 E-6	1.3 E-7 - 1.9 E-7
2d) Mixing/Loading Dry Flowable for Rights-of-Way Sprayer Application	8.2 E-7 - 1.2 E-5	4.7 E-7 - 7.0 E-6	1.6 E-8 - 2.4 E-7	2.5 E-6 - 1.2 E-5	1.4 E-6 - 7.0 E-6	4.8 E-8 - 2.4 E-7
2e) Mixing/Loading Dry Flowable for High-Pressure Handwand Application	8.2 E-7 - 1.2 E-5	4.7 E-7 - 7.0 E-6	1.6 E-8 - 2.4 E-7	2.5 E-6 - 1.2 E-5	1.4 E-6 - 7.0 E-6	4.8 E-8 - 2.4 E-7

Diuron: Handler Risk Estimates for Cancer Private Farmer/10 Exposures Per Year						
Exposure Scenario	**Typical Application Rate**			**Maximum Application Rate**		
	Cancer Risk Baseline (i.e., single layer)	**Cancer Risk (double layer + gloves + respirator)**	**Cancer Risk Engineering Controls**	**Cancer Risk Baseline (i.e., single layer)**	**Cancer Risk (double layer + gloves + respirator)**	**Cancer Risk Engineering Controls**
3a) Mixing/ Loading Wettable Powders for Aerial Application	10.0 E-4 - 2.1 E-3	5.0 E-5 - 1.1 E-4	3.3 E-6 - 7.1 E-6	1.6 E-3 - 2.7 E-3	8.0 E-5 - 1.4 E-4	5.3 E-6 - 9.1 E-6
3b) Mixing /Loading of Wettable Powders for Chemigation Application	1.0 E-3	5.0 E-5	3.3 E-6	1.6 E-3	8.0 E-5	5.3 E-6
3c) Mixing/ Loading of Wettable Powders for Groundboom Application	2.3 E-4 - 3.6 E-4	1.1 E-5 - 1.8 E-5	7.6 E-7 - 1.2 E-6	4.6 E-4 - 5.5 E-4	2.3 E-5 - 2.7 E-5	1.5 E-6 - 1.8 E-6
3d) Mixing/ Loading Wettable Powders for Rights-of-Way Sprayer Application	4.6 E-5 - 6.9 E-4	2.3 E-6 - 3.4 E-5	1.5 E-7 - 2.3 E-6	1.4 E-4 - 6.9 E-4	6.8 E-6 - 3.4 E-5	4.5 E-7 - 2.3 E-6
3e) Mixing/Loading Wettable Powders for High-Pressure Handwand Application	4.6 E-5 - 6.9 E-4	2.3 E-6 - 3.4 E-5	1.5 E-7 - 2.3 E-6	1.4 E-4 - 6.9 E-4	6.8 E-6 - 3.4 E-5	4.5 E-7 - 2.3 E-6
4) Loading Granular Formulation For Tractor-Drawn Spreader Application	5.3 E-5	8.0 E-6	1.1 E-6	5.3 E-5	8.0 E-6	1.1 E-6
Applicator						
5) Applying Sprays Aerially	See Engineering Controls	See Engineering Controls	1.4 E-6 - 3.0 E-6	See Engineering Controls	See Engineering Controls	2.2 E-6 - 3.9 E-6
6) Applying Sprays with Groundboom	1.6 E-6 - 2.4 E-6	6.2 E-7 - 9.6 E-7	2.9 E-7 - 4.5 E-7	3.1 E-6 - 3.7 E-6	1.2 E-6 - 1.5 E-6	5.8 E-7 - 7.0 E-7
7) Applying with a Rights-of-Way Sprayer	1.3 E-5 - 2.0 E-4	2.9 E-6 - 4.3 E-5	NF	4.0 E-5 - 2.0 E-4	8.6 E-6 - 4.3 E-5	NF
8) Applying with a High-Pressure Handwand	3.6 E-5 - 5.4 E-4	5.3 E-6 - 8.0 E-5	NF	1.1 E-4 - 5.2 E-4	1.6 E-5 - 8.0 E-5	NF
9) Applying Granular Formulations with a Tractor-Drawn Spreader	4.2 E-5	7.5 E-6	7.9 E-6	4.2 E-5	7.5 E-6	7.9 E-6
10) Applying Granulars with a Spoon	9.3 E-8	2.0 E-7	NF	9.3 E-8	2.0 E-7	NF

Diuron: Handler Risk Estimates for Cancer Private Farmer/10 Exposures Per Year						
Exposure Scenario	**Typical Application Rate**			**Maximum Application Rate**		
	Cancer Risk Baseline (i.e., single layer)	**Cancer Risk (double layer + gloves + respirator)**	**Cancer Risk Engineering Controls**	**Cancer Risk Baseline (i.e., single layer)**	**Cancer Risk (double layer + gloves + respirator)**	**Cancer Risk Engineering Controls**
11) Applying Granulars by Hand	**2.5 E-5**	**1.2 E-5**	**NF**	**2.5 E-5**	**1.2 E-5**	**NF**
Flagger						
12) Flagging for Spray Application	**4.1 E-6**	**2.3 E-6**	**8.3 E-8**	**6.6 E-6**	**3.6 E-6**	**1.3 E-7**
Mixer/Loader/Applicator						
13) Mixing/ Loading/ Applying Liquids using Low Pressure Handwand	**5.4 E-4**	**2.4 E-6**	**NF**	**5.4 E-4**	**2.4 E-6**	**NF**
14) Mixing/ Loading/ Applying Liquids using Backpack Sprayer	**1.8 E-5**	**9.0 E-6**	**NF**	**1.8 E-5**	**9.0 E-6**	**NF**
15) Mixing/ Loading/ Applying Wettable Powder Formulations using Low Pressure Handwand	**2.1 E-4**	**5.1 E-5**	**NF**	**2.1 E-4**	**5.1 E-5**	**NF**
16) Loading/ Applying Granulars using a Pump Feed Backpack Spreader	**1.3 E-5**	**7.8 E-6**	**NF**	**1.3 E-5**	**7.8 E-6**	**NF**
17) Loading/ Applying Granulars using a Gravity Feed Backpack Spreader	**1.1 E-4**	**5.4 E-5**	**NF**	**1.1 E-4**	**5.4 E-5**	**NF**
18) Loading/Applying Granulars with a Belly Grinder	**1.5 E-4**	**7.6 E-5**	**NF**	**1.5 E-4**	**7.6 E-5**	**NF**
19) Loading/ Applying Granules using a Push-type Spreader	**3.5 E-5**	**5.5 E-6**	**NF**	**3.5 E-5**	**5.5 E-6**	**NF**

NF = Not feasible

e. Handler Exposure from Antimicrobial Use: Mildewcide in Paints, Stains, Solvents, Adhesives, and Coatings

Diuron is used as a mildewcide in paints, solvents, adhesives, stains, polymer latices, plaster, stuccos, sealants, caulking, fillers, and coatings. These products are formulated as a flowable concentrate, a tablet, an emulsifiable concentrate, and a paste form. These pesticide products are incorporated into paint at 0.20 to 2.5 percent during the initial phase of the manufacturing process.

For the antimicrobial use of diuron, EPA considers both *"primary"* and *"secondary"* handler exposure. The primary handlers are defined as those individuals exposed to the formulated product (i.e., adding the diuron product into vats of paint during its manufacturing). The secondary handlers are defined as those individuals exposed to the active ingredient as a direct result of its incorporation into an end use product (i.e., individuals using the caulk or paint that in itself is not a registered product). The Agency has identified and assessed the primary handlers as those individuals who mix and load diuron formulation at the manufacturing facility for use as a mildewcide in adhesives, caulks, sealants, and paints. The secondary handlers are commercial applicators who apply adhesives, caulks, sealants, and paints.

No handler exposure data have been submitted to determine the extent of these exposures. The Agency assessed the risks to the primary handlers using the dermal and inhalation exposure data for loading liquids and tablet formulations from the proprietary Chemical Manufacturers Association (CMA) antimicrobial exposure study. No unit exposure data exists to assess the mixing and loading of the paste formulation into paint. It is assumed that this exposure would be similar to mixing and loading liquids into paint products. Two *primary* handler exposure scenarios have been identified and include:

(1) Mixing/Loading liquids
(2) Mixing/loading tablets

In addition to the primary handlers, secondary handlers are assessed using an airless sprayer and a paint brush. Unit exposure data used to assess the exposure resulting from applying paint containing diuron with an airless sprayer and a paintbrush were taken from a previous chlorothalonil risk assessment. These data were merged with data contained in PHED to increase the number of replicates and the quality of the unit exposure data. The surrogate data are assumed to be representative of the exposure from the use of diuron using the same equipment, since the two chemicals are formulated together in three out of the four currently registered diuron paint products. The clothing and PPE scenarios for each type of exposure reflect the clothing and PPE worn in the study from which the unit exposure values were derived. Although there is potential exposure during the application of the other treated materials (e.g., caulks and sealants), they are not included because no data are available to assess the uses. Although it is reasonable to assume that the exposure from these uses would be no greater than the exposure from use of diuron-treated paints. There is also potential for exposure from applying paint with a roller. The Agency believes that the airless sprayer and paintbrush

scenarios represent the high end exposures for diuron antimicrobial secondary uses. Two *secondary* handler exposure scenarios have been identified and include:

(3) Applying paints with an airless sprayer, and
(4) Applying paints with a paint brush.

Assumptions for the Antimicrobial Assessment:

The following additional assumptions were used in this assessment:

- Application rates - The concentration of diuron is in the paint, caulking, and other products is 0.2 to 2.5 percent. The maximum amount of diuron per gallon of paint is 0.0532 lbs ai/gallon paint.

- Amount handled - The amount of general preservatives treated per day is 100 to 1000 gallons for treated paint. The amount of paint used in the secondary exposure scenarios is 50 gallons for commercial airless sprayers and five gallons of paint for commercial painters using paint brushes/rollers.

- CMA exposure data - The CMA data for liquid products are based on transferring liquids from large containers to smaller containers for measuring and pouring. These products were applied from five to 78 minutes per application during metal cutting operations. Gloves were worn for all eight of the replicates. The CMA data for solid place (tablets, water soluble packets) had only one replicate for tablets. Again, the data used the metal fluid from a metal cutting operation. The tableted solid place data is considered low quality since there is only one replicate. No other data on adding tablets to paint or during other anti-microbial uses exists.

- In addition to diuron's mildewcide use in paints and stains, it is also used in plaster, stuccos, sealants, caulking, and fillers. Unit exposure data only exist for the use of paints/stains with airless sprayer and paintbrush. These exposure scenarios are assumed to have a higher exposure than use of diuron in plaster, stucco, sealants, caulking and fillers, since less material would be applied in a day. Therefore, the paint/stain assessment will also be considered an estimate of the exposure resulting from the use of diuron in plaster, stucco, sealants, caulking, and fillers.

- Exposure frequency - The industrial and commercial painter exposure scenarios are believed to have a short (one to 30 days) and intermediate-term (one month to 180 days) exposure duration. It is assumed that diuron would only be mixed into paint every other week, five days a week. This type of intermittent exposure frequency is not considered a chronic exposure scenario (greater then 180 days) because diuron is not believed to be used continuously for at least 180 days and urinary and fecal excretion of diuron is nearly complete within 24 hours at low-dose groups(10 mg/kg/day) and within 48 hours within high-dose groups (400 mg/kg/day) in the rat metabolism study.

- For the cancer risk assessment, workers handling diuron in the industrial setting (mixing diuron into paints) are assumed to be exposed to diuron in paints 125 days per year (50 weeks worked/year x 0.5 "every other week" x 5 days/week) and commercial painters applying diuron treated paint are assumed to be exposed 50 days per year (only in paints needing mildewcide and less than one percent of all paint is treated with diuron).

f. Handler Risk from Antimicrobial Use: Mildewcide in Paints, Stains, Solvents, Adhesives, and Coatings

The following scenarios have cancer risks between 1×10^{-4} and 1×10^{-6} at the assessed level of mitigation:

- Mixing/loading of liquids into paint products;
- Loading of tablets into paint products;
- Applying paints with an airless sprayer; and
- Applying paints with a paint brush.

Usage information gathered subsequent to the risk assessment indicates that less than 1% of all paint contains diuron. All scenarios were assessed at the maximum rate of application. Because conservative assumptions were used to develop this assessment and it is unlikely that paint containing diuron would be applied for 35 years. Because the Agency believes a 35-year exposure to diuron-treated paint is unlikely and believes the risks to workers applying paints with an airless sprayer is not of concern. Tables 18 and 19 summarize the non-cancer and cancer risks, respectively from the antimicrobial use of diuron.

Table 18. Non-Cancer Risks from Short- and Intermediate-term Antimicrobial Uses of Diuron

Exposure Scenario (Scenario #)		Clothing Attire	Inhalation Unit Exposure (µg/lb ai)[a]	Max Application Rate[b] (lb ai/gal)	Amount Treated[c]	Short-term Inhalation MOE[d,e]	Intermediate.-term Inhalation MOE[d,e]
Primary Handlers							
(1)	Mixing/loading of Liquids into Paint Products	Open pour, long pants, long-sleeved shirt, chemical resistant gloves, and a 5-fold PF dust/mist type respirator	1.7	0.0532	100 gal	77000	7700
					1,000 gal	7700	770
(2)	Loading of Tablets into Paint Products		11.8	0.0532	100 gallons	11000	1100
					1,000 gal	1100	110
Secondary Handlers							
(3) Applying Paints with an Airless Sprayer	Indoor	Long pants, long sleeved shirt, and a 5-fold PF dust/mist type respirator	470	0.0532	50 gallons	560	56
		Long pants, long sleeved shirt, gloves, and a 5-fold PF dust/mist type respirator	470			560	56
	Outdoor	Long pants, long sleeved shirt, and a 5-fold PF dust/mist type respirator	86.6	0.0532	50 gallons	3000	300
		Long pants, long sleeved shirt, gloves, and a 5-fold PF dust/mist type respirator	86.6			3000	300
(4)	Applying Paints with a Paint Brush	Long pants, long sleeved shirt, and a 5-fold PF dust/mist type respirator	101	0.0532	5 gallons	26000	2600

Footnotes:

a Inhalation unit exposures are from CMA and Chlorothalonil studies.

b Application rates are based on diuron paint labels

c Amount treated is based on assumptions from EPA's Antimicrobial Division and HED Expo SAC Policy # 9.1.[9]

d Inhalation dose (mg/kg/day) = [unit exposure (µg/lb ai) * 0.001 mg/µg unit conversion * max appl rate (lb ai/gal) * gallons handled] / Body weight (70 kg).

e MOE = NOAEL (mg/kg/day) / Daily Dose [Short-term inhalation NOAEL= 10 mg/kg/day, Intermediate-term inhalation NOAEL = 1.0 mg/kg/day]. Target MOE is 100 for occupational/commercial.

Table 19. Diuron Cancer Assessment for Antimicrobial Uses

Exposure Scenario		Clothing	Maximum Application Rate[a] (lb ai/gal)	Amount Treated[b]	Total Absorbed Dose (mg/kg/day)[c]	LADD (mg/kg/day)	Risk[e]
Primary Handlers (125 day/year)							
(1) Mixing/loading of Liquids into Paint Products		Open pour, long pants, long-sleeved shirt, chemical resistant gloves, and a 5-fold PF dust/mist type respirator	0.0532	100 gal	6.9 E-4	1.2 E-4	2.3 E-6
				1,000 gal	6.9 E-3	1.2 E-3	2.3 E-5
(2) Loading of Tablets into Paint Products			0.0532	100 gallons	2.1 E-3	3.7 E-4	7.0 E-6
				1,000 gallons	2.1 E-2	3.7 E-3	7.0 E-5
Secondary Handlers (50 day/year)							
(3) Applying Paints with an Airless Sprayer	Indoor	Long pants, long sleeved shirt, and a 5-fold PF dust/mist type respirator	0.0532	50 gallons	7.3 E-2	5.0 E-3	9.5 E-5
		Long pants, long sleeved shirt, gloves, and a 5-fold PF dust/mist type respirator			3.6 E-2	2.5 E-3	4.7 E-5
	Outdoor	Long pants, long sleeved shirt, and a 5-fold PF dust/mist type respirator	0.0532	50 gallons	5.4 E-2	3.7 E-3	7.1 E-5
		Long pants, long sleeved shirt, gloves, and a 5-fold PF dust/mist type respirator			1.7 E-2	1.1 E-3	2.2 E-5

Exposure Scenario	Clothing	Maximum Application Rate[a] (lb ai/gal)	Amount Treated[b]	Total Absorbed Dose (mg/kg/day)[c]	LADD (mg/kg/day)[d]	Risk[e]
(4) Applying Paints with a Paint Brush	Long pants, long sleeved shirt, and a 5-fold PF dust/mist type respirator	0.0532	5 gallons	4.4 E-2	3.0 E-3	5.8 E-5

a Application rates are based on diuron paint labels
b Amount treated is based on assumptions from EPA's Antimicrobial Division and HED Expo SAC Policy # 9.1.[9]
c Total daily absorbed dose (mg/kg/day) = [(dermal dose (mg/lb ai) * dermal absorption (4%)+ inhalation dose (mg/lb ai)]. See Table 6 for the corresponding dermal dose and inhalation dose.
d LADD (Lifetime average daily dose) mg/kg/day = Total daily absorbed dose (mg/kg/day) * (days worked per year/365 days per year) * (35 years worked/70 year lifetime). Days worked per year are estimates.
e Risk = LADD (mg/kg/day) * Q_1^* = 1.91e-2 (mg/kg/day

g. Handler Exposures: Algaecide Use for Use in Commercial Fish Ponds

Occupational risk assessments were conducted for the use of diuron as an algaecide in commercial fish ponds. Four short-term occupational handler scenarios were identified for the use of diuron in commercial fish production and the inhalation MOEs from all four of the commercial fish production scenarios were greater than 100 at the baseline level of mitigation and are not of concern.

Diuron is used as an algaecide in the commercial production of ornamental fish, bait fish, and catfish. For these uses, there are two state labels (FL99000200 and AR99000800), a section 18, and several other Griffin labels pending approval.

Based on the use patterns of diuron as an algaecide, four occupational exposure scenarios were identified:

(1a) Mixing/loading dry flowables for catfish production;
(1b) Mixing/loading dry flowables for ornamental fish production;
(2a) Mixing/loading wettable powders for catfish production; and
(2b) Mixing/loading wettable powders for ornamental fish production.

The assumptions used for catfish production in this assessment are assumed to be applicable to ornamental fish production as well, since no other data exist at this time. They are:

- Use instructions:

  Weigh the correct amount of Diuron 80W into a five gallon bucket and fill the bucket half full with pond water. Stir the contents of the bucket. Pour the contents of the stirred bucket into the outflow side of the aerator and rinse the bucket in the pond water. Operate the aerator for one hour after the addition of the Diuron 80W to the pond.

- The Agency assumed an average pond size of 15 acres, 4 feet deep, with 20 ponds per farm (no more than 25% would be expected to be treated per day). The assumptions on pond size and numbers of ponds per farm are based on telephone conversations between EPA staff (Pilot Interdisciplinary Risk Assessment Team) and contacts at Auburn and Mississippi State Universities in 1996.

- For commercial fish ponds treated with wettable powders, the application rates were calculated as follows. Diuron 80W, for use in catfish ponds, may be applied at a rate of 0.5 oz/acre ft (0.025 lb ai/acre ft) every seven days for a total of 9 applications. Therefore, it was estimated that handlers would mix up to 7.5 lb ai/day (15 acres/pond x 4 ft x 5 ponds/day x 0.025 lb ai/acre foot = 7.5 lb ai/day). The label AR99000800, for use in ornamental fish ponds, states an application rate of 1.0 oz/acre ft (0.05 lbs ai/acre ft). Therefore it was estimated that handlers would mix up to 15.0 lbs ai/day (15 acres/pond x 4 ft x 5 ponds/day x 0.050 lb ai/acre foot = 15.0 lb ai/day).

- For commercial fish ponds treated with dry flowables, the application rates were calculated as follows. The Nautillus Aquatic Herbicide label, for use in catfish ponds, states that it may be applied at a rate of 0.5 oz/acre ft (0.025 lb ai/acre ft) every seven days for a total of 9 applications. Therefore, it was estimated that handlers would mix up to 7.5 lb ai/day (15 acres/pond x 4 ft x 5 ponds/day x 0.025 lb ai/acre foot = 7.5 lb ai/day). The label FL99000200, for use in ornamental fish ponds, states an application rate of 0.0038 grams ai/gallon (2.73 lbs ai/acre ft), applied up to three times a year. Therefore, it was estimated that handlers would mix up to 819 lbs ai/day (15 acres/pond x 4 ft x 5 ponds/day x 2.73 lb ai/acre foot = 819 lb ai/day).

- Unit exposure data from PHED were used to assess the mixing and loading of wettable powders and dry flowables into commercial fish ponds.

h. Handler Risks: Algaecide Use for Use in Commercial Fish Ponds

With maximum PPE, (long pants, long sleeved shirt, socks, shoes, coveralls, gloves, and respirator) all four scenarios have estimated cancer risks of that range from 1.8×10^{-6} to 4.94×10^{-8} and are not of concern. Occupational postapplication exposure to diuron in treated fish production ponds is not likely to result in a risk of concern based on the extremely high dilution rate.

i. Postapplication Occupational Risk

Occupational Non-Cancer Postapplication Exposure and Risk Estimates

It should be noted that a non-cancer postapplication assessment was not conducted since no systemic toxicity by the dermal route is expected for the short- or intermediate-term durations and no post-application inhalation exposure is expected.

Occupational Cancer Postapplication Agricultural Exposure

Only crops that can receive direct foliar treatments were assessed for postapplication risks. These crops are not damaged by foliar treatments of diuron. Many of the applications of diuron are soil directed or pre-plant, since the application of diuron to most of the registered crops would result in plant damage. The crops assessed are oats; forage; oats, grain; oats, hay; oats, straw; wheat, forage; wheat, grain; wheat, hay; wheat straw; birdsfoot trefoil, forage; birdsfoot trefoil, hay; grass, forage, except Bermuda grass; grass, hay, except Bermuda grass; alfalfa, forage; alfalfa, hay; asparagus; clover, forage; clover, hay; pineapple; and sugarcane.

EPA has determined that there are potential postapplication exposures to individuals entering treated fields. In the Worker Protection Standard, a restricted entry interval (REI) is defined as the duration of time which must elapse before residues decline to a level so entry into a previously treated area and engaging in any task or activity would not result in exposures which are of concern. Typically, the activity with the highest risk will drive the selection of the appropriate REI for the crop. The current diuron labels have a REI requirement of 12 hours with the following early entry PPE required: coveralls over long sleeved shirt and long pants, waterproof gloves, chemical resistant footwear plus socks, protective eye wear and chemical resistant headgear for overhead exposures.

Significant exposure to diuron may result from contact with treated soil when planting seedlings, moving irrigation lines, or other soil related activities since diuron is applied directly to the soil. At this time, no transfer coefficients exist for activities resulting in contact with treated soil. There are also no data on the soil residue dissipation of diuron. A worker exposure study and a diuron soil residue dissipation study would be needed to assess this risk. Transfer coefficients do not exist for the mechanical harvesting of alfalfa and asparagus and these activities are considered of special concern according to the Agriculture Transfer Coefficient Exposure

SAC policy 3.1. Significant worker exposure is possible from mechanical harvesting these crops.

Since diuron can be applied as a defoliant soon before harvest, exposure to cotton harvesters is of special concern for this chemical. According to data recently submitted to the Agency, there is exposure during the mechanical harvesting of cotton. Exposure can result from the following occupational job functions: picker operator, module builder, tramper, and raker. A picker operator is the individual that drives the harvesting machine, usually with an enclosed cab. A module builder operator is the individual that operates the controls of the module builder that the picker dumps the cotton into. The module builder is used to receive the cotton and then compact it into modules or bales. A tramper is the individual who stands on top of the module builder and helps direct the cotton out of the picker and into the module builder. The tramper than jumps into the module builder and redistributes the cotton around inside. A raker is the individual who rakes up the spilled cotton and puts it back into the module builder. The models presently used to assess occupational postapplication exposure cannot be used since the foliage has dropped off of the cotton plants by the time of harvest. There are no standard default transfer coefficients for these activities at this time.

Chemical-specific postapplication exposure and/or environmental fate data have not yet been submitted by the registrant in support of reregistration of diuron. In lieu of these data, a surrogate postapplication assessment was conducted to determine potential risks. The surrogate assessment is based on both the typical and maximum application rates that a private farmer/grower may reasonably be expected to be exposed to for a short-term duration (10 days), and on the typical application rates that a commercial applicator may be reasonably expected to be exposed to for a longer-term duration (30 days). The maximum application rates are not included in the postapplication assessment for the commercial applicator, as it is unlikely that a commercial applicator would be exposed at the maximum application rate for 30 days a year.

Occupational Data Sources and Assumptions

(1) Data Sources

- Typical application rates were supplied by the primary registrant, Griffin. The sources of the data were quoted as Doane, the National Center for Food and Agricultural Policy (NCFAP), the U. S. Department of Agriculture, and Griffin. A range of the typical application rates was given. The highest value of the typical range of application rates was used in this assessment. BEAD has evaluated the typical application rates and determined that they are typical to high end. No data on the typical application rates of paints, ponds, and non-crop/industrial areas were supplied. Therefore, only the maximum application rates were used in the cancer assessments for these uses.

- No chemical specific DFR data exists for diuron. Therefore, the DFR values are derived from using an estimated 20 percent of the rate applied as initial dislodgeable residues for cotton and an estimated 10 percent dissipation rate per day.

- The transfer coefficients used in this assessment are from the Agricultural Re-entry Task Force (ARTF) database. An interim transfer coefficient policy was developed by HED's Science Advisory Council for Exposure using the ARTF database (policy # 3.1). It is the intention of HED's Science Advisory Council for Exposure that this policy will be periodically updated to incorporate additional information about agricultural practices in crops and new data on transfer coefficients. Much of this information will originate from exposure studies currently being conducted by the ARTF, from the further analysis of studies already submitted to the Agency, and from the studies in the published scientific literature.

(2) Assumptions

The following assumptions were used in the occupational postapplication assessment.

- The maximum transfer coefficients for each crop were used to determine the highest possible postapplication exposure. Other activities, such as scouting and irrigation, were also assessed to determine possible exemptions to the restricted entry intervals calculated for the highest postapplication exposures.

- Exposure time is assumed to be 8 hours per day. This represents a typical work day.

- The average body weight of 70 kg is used.

- Exposures per year: Ten days of exposure per year was assumed for the private grower and 30 days of exposure per year was assumed for a commercial applicator.

- Maximum application rates were used in the private grower assessment. Typical application rates were used in both the private grower and commercial applicator assessments. It is assumed that as the frequency of exposure increases, the probability of being exposed to a maximum residue resulting from the maximum application rate decreases. Therefore, maximum application rates were only assessed for the professional grower.

Occupational Postapplication Cancer Risk Summary

When evaluating cancer risks for the occupational population, EPA closely examines risks in the $1x10^{-4}$ to $1x10^{-6}$ range and seeks cost effective ways to reduce occupational cancer risks to the greatest extent feasible, preferably $1x10^{-6}$ or less. This diuron postapplication cancer assessment assumes that a worker would contact residues on the day of application for ten or thirty days a year, every year for 35 years. Since it is unlikely that a postapplication worker would contact the highest possible residue value for that length of time, this assessment is considered very conservative.

Private Growers (10 Days Exposure Per Year)

Postapplication cancer risks for private growers were calculated at both the typical application rate and the maximum application rate for each crop grouping. As mentioned previously, the occupational cancer risk assessment is a conservative assessment; therefore, all cancer risks to private growers were less than 1×10^{-4} on the day of treatment and are not of concern.

Commercial Farm Workers (30 Days Exposure Per Year)

Postapplication cancer risks for commercial farm workers were calculated at the typical application rate only for each crop grouping. All cancer risks to commercial farm workers were less than 1×10^{-4} on the day of treatment and are not of concern.

Historically, setting REIs on cancer endpoints has been difficult because of the need for lifetime use assumptions. To estimate the LADD (Life-time Average Daily Dose) the typical application rate, the number of days worked per year, and the number of years one would be exposed during a working lifetime are needed. Each one of these variables is dependent upon many factors. For example, the number of days worked per year must correspond to the days worked when the pesticide of concern has been applied. Additionally, the residue dissipation over the work interval should be estimated. Without an estimate for residue dissipation one needs to assume (conservatively) that the worker travels from one treated field to another so that the highest residue value is always contacted. In the case of diuron, a screening estimate was developed because lifetime use data are not available.

Occupational Postapplication Exposures to Paint Containing Diuron

Postapplication exposures may occur in industrial settings around open vats used in paint processing. Inhalation and dermal exposures may also occur while maintaining industrial equipment. No postapplication exposure data have been submitted to determine the extent of postapplication exposures in the industrial settings. However, usage information gathered subsequent to the risk assessment indicates that less than 1 % of all paint contains diuron. Inhalation exposures are expected to be minimal because of the low vapor pressure of diuron (2×10^{-7} mmHg at 30 °C) and aerosol formation is not expected to be registered. Dermal postapplication exposures are expected to be lower than when handling/loading the formulated product. Therefore, postapplication exposures in the industrial settings are expected to be minimal and not of concern.

Occupational Postapplication Exposures to Commercial Fish Ponds

Diuron is applied to ponds/aquariums in the form of a liquid or an effervescent tablet. Due to the high dilution rate of the liquid in pond and aquarium water (0.0000074 lb ai per gallon of water), and the effervescent nature of the tablet (expected to dissolve in less than five minutes), postapplication exposure to diuron in pond and aquarium water is expected to be minimal.

Furthermore, postapplication activities in and around ponds/aquariums treated with diuron are assumed to be infrequent.

j. Human Incident Data

The Agency searched several databases for reports of incidents resulting from exposures to diuron. The databases searched were the Incident Data System (IDS), American Association of Poison Control Centers (AAPCC), California Pesticide Illness Surveillance Program, and National Pesticide Telecommunication Network (NPTN). There were incidents reported involving both adults and children. Most were treated on an outpatient basis but a few required hospitalization and one death occurred. A direct connection between exposure to diuron as the cause and the reported death has not been made. Some incident reports described symptoms such as eye irritation, rash, dizziness, respiratory irritation and headaches for both agricultural and non-agricultural exposures. Specific details may be found in, "Review of Diuron Poisoning Incident Data. Chemical: # 035505," dated October 11, 2001.

The incident data show that the number of poisoning incidents for diuron alone is relatively small in any one surveillance system. Also, the incidents are scattered in time and location, and many of the incidents involve diuron use in mixtures. Therefore, few conclusions can be drawn. However, a 1995 Louisiana elementary school incident in which diuron was associated with the illnesses of 23 children and 9 adults, remains unexplained. There are no known recreational or school building registered uses of diuron.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. For detailed discussions of all aspects of the environmental risk assessment, see the "Environmental Risk Assessment for the Reregistration of Diuron", dated August 27, 2001, the "Drinking Water Reassessment for Diuron and its Degradates", dated March 11, 2002, and the memorandum entitled, "Surface Water Monitoring Data for Diuron" dated August 5, 2003. These documents are also available in the OPP public docket and on the Agency's website at: *http://cfpub.epa.gov/oppref/rereg/status.cfm?show=rereg*.

1. Environmental Fate and Transport

The environmental fate database for diuron is essentially complete. Diuron is mobile and has the potential to leach to ground and to contaminate surface waters. An upgradable adsorption/desorption/leaching study (MRID 44490501) showed that diuron has low to medium K_{oc} values (468-1666) and Freundlich K_{ads} values (7.9-28). In addition, diuron has relatively low water solubility (42 ppm) and low volatility (2×10^{-7} mm Hg at 30˚C).

Diuron is persistent in terrestrial environments. The major routes of dissipation for diuron in the environment is microbial degradation in water. Diuron also degrades through photolysis in both water and soil, but at a slower rate.

Diuron is stable to hydrolysis at pH 5, 7, and 9. The minor degradate 3,4-dichloroaniline (3,4-DCA) was identified in all hydrolysis test solutions (0.5% of applied). In aqueous and soil photolysis studies with diuron, calculated half-lives were 43 and 173 days, respectively. In water, photolysis degradates were carbon dioxide (CO_2) and at least 13 minor (each < 9% of applied) polar products. In soil, the major photolysis degradate was N'-(3,4-dichlorophenyl)-N-methylurea (DCPMU), and the minor degradates were demethylated DCPMU (DCPU), dichloroaniline (DCA), and 3,3',4,4'-tetrachlorobenzene (TCAB). The calculated half-lives in aerobic and anaerobic soil metabolism studies were 372 (aerobic) and 1000 (anaerobic) days. Under aerobic conditions, the major degradate was DCPMU (20.9-22.5 % of the amount applied at 365 days), and minor degradates were DCPU and CO_2. Under anaerobic conditions, the only degradate identified was DCPMU, which accounted for a maximum of 10.3% of applied (at 45 days).

In contrast to its persistence in laboratory studies of hydrolysis, aqueous and soil photolysis, and aerobic and anaerobic soil metabolism, diuron degraded relatively quickly in aquatic metabolism laboratory studies, with a half-life of 33 days under aerobic conditions and of 5 days under anaerobic conditions. The major metabolism degradate under aerobic conditions was N'-(3-chlorophenyl)-N,N-dimethylurea (MCPDMU) which reached 25 % of the applied dose by the end of the study and was evenly distributed between the soil and aqueous phase. The minor degradates identified were DCPMU and CPMU and were primarily associated with the soil phase. The major degradate under anaerobic conditions was MCPDMU, which was mainly associated with the aqueous phase. The two minor degradates were PDMU and MCPMU.

In terrestrial field dissipation studies in FL, MS, and CA with sand, silt loam, and silty clay loam soils, diuron dissipated in bare ground plots with half-lives of 73, 139, and 133 days, respectively. The major degradate DCPMU dissipated in the same plots with half-lives of 217, 1733, and 630 days. In aquatic field dissipation studies, half-lives were 115-177 days and the major degradate was DCPMU.

The major degradate formed in laboratory studies of soil photolysis, aerobic soil metabolism, and anaerobic soil metabolism, and in all field dissipation studies was DCPMU. The major degradate formed in laboratory studies of aerobic and anaerobic aquatic metabolism studies was MCPDMU. The major and minor degradates of diuron are shown in Table 20. The environmental degradates of toxicological concern to humans and other non-target species are shown in italics.

The degradate 3,4-DCA is of toxicological concern for human health and is a common degradate for diuron, linuron, and propanil. Based on limited environmental fate data (three hydrolysis studies), 3,4-DCA is formed at <1% of applied diuron. Although the environmental risk assessment for diuron noted the lack of fate and transport data on 3,4-DCA, additional data will not be required for diuron since this degradate is formed at such a low percent of applied parent.

Tetrachloroazobenzene (TCAB), also a degradate of concern for human health, was identified as one of the minor degradates of diuron in a soil photolysis study with a maximum concentration of 0.038 ppm.

Table 20. Major and Minor Degradates of Diuron in Environmental Fate Studies

Environmental Fate Study	Major degradate	Minor degradates
Hydrolysis (MRID 41418804)	None	*3,4-DCA*
Photodegradation in Water (MRID 41418805)	CO_2	13 polar products
Photodegradation in Soil (MRID 41719302)	DCPMU	DCPU, *3,4-DCA*, *TCAB*
Aerobic Soil Metabolism (MRID 4179303)	DCPMU	DCPU, CO_2
Anaerobic Soil Metabolism (MRID 41418806)	DCPMU	None
Aerobic Aquatic Metabolism (MRID 44221002)	MCPDMU	DCPMU, CPMU
Anaerobic Aquatic Metabolism (MRID 44221001)	MCPDMU	PDMU, MCPMU
Terrestrial Field Dissipation (MRIDs 44654001, 44865001)	DCPMU	Not Measured
Aquatic Field Dissipation (MRIDs 43762901, 43978901)	DCPMU	Not Measured

2. Toxicity (Hazard) Assessment

a. Toxicity to Terrestrial Organisms

Diuron is sightly toxic to bobwhite quail and practically nontoxic to mallard duck on an acute oral basis. It is practically nontoxic to bobwhite quail and slightly toxic to mallard duck on a subacute dietary basis. Diuron is relative nontoxic to both honey bees and laboratory rats (acute basis). In a 2-generation rat reproduction study, diuron caused pup body weight loss. No avian reproduction study was submitted by the registrant and one is required because diuron is persistent in the environment and has the potential to cause chronic effects. In Table 21, the toxicity endpoints used in calculating risk are shaded.

Table 21. Summary of Acute and Chronic Toxicity Values for Terrestrial Organisms

Species	Acute Toxicity				Chronic Toxicity	
	Acute LD_{50} (mg/kg)	Acute Oral Toxicity (MRID)	Subacute LC_{50} (ppm)	Subacute Dietary Toxicity (MRID)	NOEC/ LOEC (ppm) (MRID)	Affected endpoint
Northern bobwhite quail *Colinus virgianus*	940	Slightly toxic (50150170)	>5000	Practically nontoxic (00022923)	–	--
Mallard duck *Anas platyrhynchous*	>2000	Practically nontoxic (00160000)	1730	Slightly toxic (00022923)	--	--
Honey bee *Apis meliferus*	145[1]	Practically nontoxic (00036935)	–	–	–	--
Laboratory rat *Rattus norvegicus*	Male: 5,000 Female: 10,000	Class. III (00146145)	–	--	NOEC =250 LOEC = 1750 (00146145)	Pup body weight

b. Toxicity to Aquatic Organisms

Diuron is moderately toxic to the majority of aquatic animals tested, including rainbow trout, bluegill sunfish, water flea, striped mullet, sheepshead minnow, Eastern oyster, and brown shrimp. However, it is highly toxic to cutthroat trout and scuds. Diuron is only slightly acutely toxic to fathead minnows. In chronic studies, diuron reduced the number of surviving fathead minnows, the growth and survival of sheepshead minnows, and the growth and reproduction of mysid shrimp. Chronic studies on water fleas and sheepshead minnows will need to be repeated because they failed to provide a LOEC (water flea, no observed effect at all doses tested) or a NOEC (sheepshead minnow, reduced growth and survival at all doses tested). In Table 22, the toxicity endpoints used in calculating risk are shaded.

Table 22. Summary of Acute and Chronic Toxicity Values for Aquatic Organisms

Species	Acute Toxicity			Chronic Toxicity	
	48-h EC_{50} (ppm)	96-hr LC_{50} (ppm)	Acute Toxicity (MRID)	NOEC/LOEC (ppm)	Affected Endpoint (MRID)
Cutthroat trout *Oncerynchus clarki* (freshwater fish)	–	0.71	Highly toxic (40098001)	–	--
Fathead minnows *Pimephales promelas* (freshwater fish)	–	14	Slightly toxic (00141636)	NOEC = 0. 026 LOEC = 0.062	No. of survivors (00141636)
Scud *Gammmarus fasciatus* (freshwater invertebrate)	0.16	–	Highly toxic (40094602)	–	--
Water flea *Daphnia magna* (freshwater invertebrate)	1.4	–	Moderately toxic (40094602)	NOEC = 0. 2 No LOEC	No effect (STODIV05)
Striped mullet *Mugil cephalus* (marine/estuarine fish)	–	6.3	Moderately toxic (40228401)	–	--
Sheepshead minnow *Cypprinoden varieggatus* (marine/estuarine fish)	–	6.7	Moderately toxic (41418805)	No NOEC LOEC = 0.44	Reduced growth, survival (42312901)
Brown shrimp *Penaeus aztecus* (marine/estuarine invertebrate)	1	–	Moderately toxic (40228401)	–	–
Mysid shrimp *Americamysis bahia* (marine/estuarine invertebrate)	–	--	–	NOEC = 0.27 LOEC = 0.56	Growth Reproduction

c. Toxicity to Non-target Plants

Tier II terrestrial plant seedling emergence and vegetative vigor toxicity studies were conducted with four species of monocotyledonous plants (corn, onion, sorghum, and wheat) and six species of dicotyledonous plants (soybean, pea, rape, cucumber, sugar beet, and tomato). Onion and tomato were most sensitive species for seedling emergence; and wheat and tomato were most sensitive species for plant vegetative vigor. Tier II aquatic plant toxicity testing was conducted on fifteen species of nonvascular plants including aquatic algae and diatoms. However, only one study on green algae (*Selenastrum capricornutum*) was acceptable because the other submitted studies tested inappropriate species. No vascular aquatic plant studies were submitted for diuron; an aquatic plant study on four species including the vascular plant *Lemna gibba*

(duckweed) is required. Tables 23 and 24 show a summary of acute toxicity values for non-target terrestrial plants and non-target aquatic plants, respectively.

Table 23. Summary of Acute Toxicity Values for Non-Target Terrestrial Plants (Endpoint = Shoot Dry Weight).

Classification	Toxicity test	Crop (MRID)	EC_{25}/EC_{05} (lbs. ai/A)
Monocot	**Seedling emergence**	Onion (MRID 44114301)	0.099/ 0.089
	Vegetative vigor	Wheat (MRID 44113401)	0.021/ 0.002
Dicot	**Seedling emergence**	Tomato (MRID 44113401)	0.08 /0.047
	Vegetative vigor	Tomato (MRID 42398501)	0.002/ 0.001

Table 24. Summary of Acute Toxicity Values for Non-Target Aquatic Plants

Classification	Species (MRID)	EC_{50} (ppb)
Non-vascular	Green algae *Selenastrum capricornutum* (MRID 42218401)	2.4
Vascular	Duckweed *Lemna Gibba* (No study available)	None available

3. Exposure and Risk Assessment

a. Risk Calculation

Levels of Concern

To evaluate the potential ecological risk to non-target organisms from the use of diuron products, risk quotients (RQs) are calculated from the ratio of estimated environmental concentrations (EEC) to ecotoxicity values. The Agency calculates risk quotients (RQs) by dividing exposure estimates by acute and chronic ecotoxicity values:

RQ = EXPOSURE/TOXICITY

RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to nontarget organisms and the need to consider regulatory action. The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on non-target organisms. Risk presumptions, along with the corresponding LOCs, are given in Table 25.

Table 25. Risk Presumptions for Terrestrial and Aquatic Animals

Risk Presumption	LOC terrestrial animals	LOC aquatic animals	LOC terrestrial plants	LOC aquatic plants
Acute High Risk there is potential for acute risk; regulatory action may be warranted in addition to restricted use classification,	0.5	0.5	1	1
Acute Restricted Use -there is potential for acute risk, but may be mitigated through restricted use classification,	0.2	0.1	1	1
Acute Endangered Species -endangered species may be adversely affected; regulatory action may be warranted,	0.1	0.05	1	1
Chronic Risk -there is potential for chronic risk; regulatory action may be warranted.	1	1	NA	NA

When available, field studies and incident data are used to further characterize the risk to non-target organisms. Risk characterization integrates the results of all available data to evaluate the likelihood of adverse ecological effects.

b. Exposure and Risk to Non-target Terrestrial Organisms

(1) Avian Risk

In order to assess risk to birds, estimated environmental concentrations (EECs) on food items following product application are compared to LC_{50} values to assess risk by the Risk Quotient (RQ) method. Estimates of maximum and average residue levels (EECs) of diuron on avian food items were based on the nomograph of Hoerger and Kenega (1972), as modified by Fletcher et al. (1994). The upper limit values from the nomograph represent the 95th percentile of residues from actual field measurements (Hoerger, 1972). The Fletcher et al. (1994) modification to the Kenaga nomograph are based on measured field residues from 249 published research papers, including 118 various species of plants, 121 pesticides, and 17 chemical classes. These modifications represent the 95th percentile of the expanded data set.

Avian risk quotients are calculated using the most sensitive LC_{50} (acute risk) and NOEC (chronic risk) for birds. In this instance, the mallard duck 5-day LC_{50} of 1730 ppm was used to calculate acute risk. Short grass represents the food items with the highest residue concentration and therefore, the highest RQ, conversely, seeds represent the foodstuffs with the lowest RQs. Other food items fall within this range. Chronic risk to birds could not be calculated because no chronic avian toxicity data were available for diuron; an avian reproduction study is required.

The highest calculated avian acute RQ is 1.7 and is based on a single application of diuron at 12 lbs a.i./A to rights-of-way. The highest RQ associated with an agricultural use is 1.3, based on a single ground application of 9.6 lbs a.i./A to grapes, or two applications of 4.8 lbs a.i./A to citrus. Acute (LOC = 0.5), acute high risk (LOC = 0.2), and acute endangered species (LOC = 0.1) levels of concern are exceeded for birds feeding on short grass, tall grass (not shown) and broadleaf plants and insects (not shown). However, LOCs are not exceeded if RQs are calculated using mean EECs (not shown) based on mean residues from Hoerger and Kenega 1972 as modified by Fletcher et al. 1994. Table 26 shows the range of acute avian RQs based on maximum EECs and maximum labeled application rates for birds feeding on short grass and seeds, only.

Table 26: Avian Acute Risk Quotients for Single and Multiple Applications Based on Maximum Residues (LC_{50} = 1730 ppm).

Use site/ application methods (number of applications)	Rate (lbs ai/A)	Food Items	Single Application	Multiple Applications
			Acute only	Acute only
Rights-of-way/aerial (1)	12	Short grass	1.7	--
		Seeds	0.1	–
Grapes/ground (1)	9.6	Short grass	1.3	--
		Seeds	0.08	–
Citrus/ground (2)	6.4 (4.8 for 2 applications)	Short grass	0.9	1.3
		Seeds	0.06	0.08
Fruits/ground (1)	4.0	Short grass	0.6	--
		Seeds	0.03	--
Sugarcane/aerial (3)	3.2	Short grass	0.4	0.8
		Seeds	0.03	0.05
Cotton/aerial (2)	1.6 (1.2 for 2 applications)	Short grass	0.2	0.3
		Seeds	0.01	0.02

(2) Mammalian Risk

In order to assess risk to small mammals, estimated environmental concentrations (EECs) of diuron on food items are compared to LC_{50} values from laboratory studies on small mammals (rats, mice) to calculate risk quotients (RQs). Wild mammal toxicity studies are required on a case-by-case basis, depending on the results of laboratory mammalian studies, intended chemical use patterns and pertinent environmental fate characteristics. For most chemicals, including diuron, rat or mouse toxicity values obtained from the Agency's Health Effects Division substitute for wild mammal testing.

To calculate acute risk and maximum chronic risk values, estimates of maximum residue levels (EECs) of diuron on mammalian food items were based on the model of Hoerger and Kenega (1972), as modified by Fletcher et al. (1994). In addition, a second estimate of maximum chronic risk values and an estimate of average chronic risk values were calculated using the L-FATE model.

The concentration of diuron in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the LD_{50} value (in this case, the male rat 5-day LD_{50} of 5,000 mg/kg) by the % (decimal of) body weight consumed (95% for grass, forage, and insects, and 21% for seeds). An acute risk quotient is then determined by dividing the EEC by the derived LC_{50} value. Chronic risk quotients are calculated in a similar manner using the most sensitive chronic endpoint, in this case, a NOEC of 250 ppm from a 2-generation rat reproduction study (chronic effect = pup body weight loss). Risk quotients are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds).

The acute level of concern (LOC = 0.5) for mammals is only exceeded for 15 g mammals feeding on short grass following a 12 lb a.i./A application of diuron to rights-of-way, a use which results in the highest calculated RQ for mammals, 0.6. The highest calculated RQ associated with an agricultural use is 0.4, for a single ground application to grapes of 9.6 lbs a.i./A, two ground applications of 4.8 lbs a.i./A to citrus, or three applications of 3.2 lbs a.i./A to sugarcane. Acute high risk (LOC = 0.2) and acute endangered species (LOC = 0.1) levels of concern are exceeded for small (15 g) and medium-sized (35 g) mammals for some use-sites and application rates.

The chronic level of concern (LOC = 1) for mammals is exceeded for small (15 g) mammals feeding on short grass, tall grass, and broadleaf plants and insects, for all crops with multiple diuron applications (citrus, sugarcane, and cotton). The highest calculated chronic RQ value is 9.2, based on 2 ground applications (4.8 lbs a.i./A per application) to citrus and 3 aerial applications (3.2 lbs a.i./A per application) to sugarcane.

Table 27 shows the acute and chronic risk quotients for the smallest mammals (15 g, most sensitive, highest risk) feeding on seeds (lower residues and risk) and short grass (highest residues and risk) calculated using maximum Kenaga nomogram residues, only. These values represent the most conservative estimate of risk (highest RQs).

Table 27: Mammalian (15 g mammal) Acute and Chronic Risk Quotients for Single and Multiple Applications Based on Maximum Residues (LD_{50} = 5,000 mg/kg, NOEC = 250 ppm).

Use site/ application methods (number of applications)	Rate (lbs ai/A)	Food Items	Single Application		Multiple Applications	
			Acute	Chronic	Acute	Chronic
Rights-of-way/aerial (1)	12	Short grass	0.6	--	--	--
		Seeds	0.01	--	--	--
Grapes/ground (1)	9.6	Short grass	0.4	--	--	--
		Seeds	< 0.01	--	--	--
Citrus/ground (2)	6.4 (4.8 for 2 applications	Short grass	0.3	--	0.4	9.2 (3.1)[1]
		Seeds	< 0.01	--	< 0.01	0.6 (0.3)[1]
Fruits/ground (1)	4.0	Short grass	0.2	--	--	--
		Seeds	< 0.01	--	--	--
Sugarcane/aerial (3)	3.2	Short grass	0.2	--	0.4	9.2 (2.1)[1]
		Seeds	< 0.01	--	< 0.01	0.6 (0.2)[1]
Cotton/aerial (2)	1.6 (1.2 for 2 applications)	Short grass	0.07	--	0.1	2.1 (0.8)[1]
		Seeds	< 0.01	--	< 0.01	0.1 (0.06)[1]

[1]Value in parentheses is the average chronic RQ, calculated using average residue values from the FATE model.

(3) Risk to Non-target Insects

Diuron is practically non-toxic to honeybees and risk to non-target insects is expected to be minimal.

c. Exposure and Risk to Non-target Aquatic Organisms

(1) Surface Water Resources Assessment

Diuron aquatic estimated environmental concentrations (EECs) were generated using the Tier I surface water model GENEEC II, a screening level model generating upper-bound EECs. Diuron EEC values were calculated based on applications to various crops using aerial or ground equipment. In addition, the Tier II surface water model PRZM/EXAMS was used to generate less conservative EEC values for the grape (CA), citrus (FL) and apple (NY) diuron use scenarios. These scenarios were chosen to reflect a wide range of diuron application rates and regional weather conditions.

(2) Risk to Fish and Aquatic Invertebrates

Risk to freshwater fish and invertebrates

To calculate acute RQs for freshwater aquatic organisms, peak EEC values were divided by the most sensitive acute toxicity endpoints: the cutthroat trout LC_{50} (0.71 ppm) for fish, and the scud LC_{50} (0.16 ppm) for invertebrates. Chronic RQ values were calculated by dividing 21-day average EECs (for invertebrates) and 60-day average EECs (for fish) by the most sensitive chronic toxicity endpoints: the fathead minnow NOEC (0.0264 ppm) for fish, and the water flea NOEC (0.2 ppm) for invertebrates.

The acute level of concern for aquatic organisms (LOC = 0.5) is not exceeded for freshwater fish except for the 12 lbs a.i./A right-of-way use, which results in the highest calculated RQ for freshwater fish, 0.6 (Table 28). However, the acute restricted use level of concern (LOC = 0.1) is exceeded for freshwater fish for all uses except sugarcane (multiple applications) and cotton (single and multiple applications). The acute endangered species level of concern (LOC = 0.05) is exceeded for freshwater fish for all uses except multiple applications to cotton.

The highest acute RQ for freshwater invertebrates is 2.6 and is associated with the use of diuron on rights-of-way. The acute LOC (0.5) is exceeded for freshwater invertebrates for all uses except sugarcane (multiple applications) and cotton (single and multiple applications). The acute restricted use (0.2) and acute endangered species (0.05) levels of concern are exceeded for all uses.

The highest calculated chronic RQs for freshwater fish are 9.0 (rights-of-way) and 7.2 (grapes), and the highest calculated RQs for freshwater invertebrates are 1.8 (rights-of-way) and 1.3 (grapes). The chronic level of concern for aquatic organisms (LOC = 1) is exceeded for freshwater fish for all uses except multiple applications to cotton. For invertebrates, the chronic LOC (1) is exceeded for single applications to rights-of-way and grapes, and for multiple applications to citrus.

Table 28. Freshwater Fish and Invertebrate Acute and Chronic Risk Quotients

Use site/ application methods (number of applications)	Rate (lbs ai/A)	Acute Risk Quotients		Chronic Risk Quotients	
		Freshwater Fish	Freshwater Invertebrates	Freshwater Fish	Freshwater Invertebrates
Rights-of-way/aerial (1)	12	0. 6	2. 6	9.0	1.8
Grapes/ground (1)	9.6	0.5 (0.05)[1]	2. 1 (0.2)[1]	7. 2 (1.4)[1]	1.3 (0.2)[1]
Citrus/ground (1)	6.4	0.3 (0.2)[1]	1.4 (0.9)[1]	4.8 (4.9)[1]	0.9 (0.7)[1]
Citrus/ground (2)	4.8	0.1	0.6	2.0	1.2
Fruits/ground (1)	4.0	0.2 (0.07)[1]	0.9 (0.3)[1]	3.0 (1.9)[1]	0.5 (0.3)[1]
Alfalfa, sugarcane, grass seeds/aerial (1)	3.2	0.2	0.7	2.5	0.6
Sugarcane/aerial (3)	3.2	0.09	0.4	1.4	0.8
Cotton/aerial (1)	1.6	0.08	0.4	1.3	0.2
Cotton/aerial (2)	1.2	0.03	0.1	0.5	0.3

[1] RQ values in parentheses were calculated using Tier II PRZM/EXAMS modeling.

Risk to estuarine/marine fish and invertebrates

To calculate acute RQ values for estuarine/marine aquatic organisms, peak EEC values were divided by the most sensitive acute toxicity endpoints: the striped mullet LC_{50} (6.3 ppm) for fish, and the brown shrimp LC_{50} (>1 ppm) for invertebrates. Chronic RQ values were calculated by dividing 21-day average EECs (for invertebrates) and 60-day average EECs (for fish) by the most sensitive chronic toxicity endpoints: the sheepshead minnow NOEC (0.44 ppm) for fish, and the mysid shrimp NOEC (0.27 ppm) for invertebrates.

The acute (LOC = 0.5) and acute restricted use (LOC = 0.1) levels of concern for aquatic organisms are not exceeded for estuarine/marine fish (Table 29). The acute endangered species level of concern (LOC = 0.05) is exceeded for estuarine/marine fish only for the uses on rights-of-way (RQ = 0.07) and grapes (RQ = 0.05). The acute LOC (0.5) is not exceeded for estuarine/marine invertebrates. The calculated RQs associated with a single application of diuron to rights-of-way (RQ = 0.4), grapes (RQ = 0.3), and citrus (RQ = 0.2) exceed the acute restricted use level of concern (0.2) for invertebrates. The acute endangered species (0.05) level of concern is exceeded for estuarine/marine invertebrates, for all uses except multiple applications to cotton.

The highest calculated chronic RQ for estuarine/marine fish is 0.5 (rights-of-way use), which does not exceed the chronic level of concern (1). The highest calculated chronic RQs for

estuarine/marine invertebrates are 1.3 (rights-of-way) and 1.0 (grapes); these are the only uses with RQs that exceed the chronic LOC of 1.

Table 29. Estuarine/Marine Fish and Invertebrate Acute and Chronic Risk Quotients

Use site/ application methods (number of applications)	Rate (lbs ai/A)	Acute Risk Quotients		Chronic Risk Quotients	
		Estuarine/ Marine Fish	Estuarine/ Marine Invertebrates	Estuarine/ Marine Fish	Estuarine/ Marine Invertebrates
Rights-of-way/aerial and ground (1)	12	0. 07	0.4	0.5	1.3
Grapes/ground (1)	9.6	0.05 (0.006)[1]	0.3 (0.04)[1]	0.4 (0.08)[1]	1.0 (0.1)[1]
Citrus/ground (1)	6.4	0.03 (0.02)[1]	0.2 (0.1)[1]	0.3 (0.3)[1]	0.06 (0.5)[1]
Citrus/ground (2)	4.8	0.01	0.09	0.1	0.9
Fruits/ground (1)	4.0	0.02 (0.008)[1]	0.1 (0.05)[1]	0.2 (0.1)[1]	0.4 (0.2)[1]
Alfalfa, sugarcane, grass seeds/aerial and ground (1)	3.2	0.02	0.1	0.2	0.4
Sugarcane/aerial (3)	3.2	0.01	0.06	0.08	0.6
Cotton/aerial (1)	1.6	0.01	0.06	0.08	0.2
Cotton/aerial (2)	1.2	0.01	0. 02	0.03	0.2

[1] RQ values in parentheses were calculated using Tier II PRZM/EXAMS modeling.

d. Exposure and Risk to Non-target Terrestrial and Aquatic Plants

Risk to non-target terrestrial plants

Terrestrial plants inhabiting dry and semi-aquatic areas may be exposed to diuron from runoff, spray drift. Semi-aquatic areas are those low-lying wet areas that may be dry at certain times of the year. The run-off scenario used for dry areas is characterized as “sheet run-off”; the run-off scenario for semi-aquatic areas is characterized as "channelized run-off". EECs are calculated for ground and aerial applications. Spray drift exposure from ground application is assumed to be 1% of the application rate, whereas spray drift from aerial applications is assumed to be 5% of the application rate. The total loading to dry areas adjacent to treatment sites is the sum of sheet run-off and drift (EEC_{dry}). The total loading to semi-aquatic areas is the sum of channelized run-off and drift ($EEC_{semi\text{-}aquatic}$).

In order to calculate the acute RQs for terrestrial plants in dry areas adjacent to diuron application sites, the EEC_{dry} was divided by the EC_{25} value of the most sensitive species in the seedling emergence study (tomatoes, EC_{25} = 0.08 lbs a.i./A). The acute RQs for terrestrial plants in semi-aquatic areas were calculated by dividing the $EEC_{semi\text{-}aquatic}$ by the EC_{25} value of the most sensitive species in the seedling emergence study (tomatoes, EC_{25} = 0.08 lbs a.i./A).

Acute RQs for endangered terrestrial plants are calculated in the same manner as for non-endangered plants, except that the EC_{05} values for the most sensitive species in the seedling emergence (tomato, EC_{05} = 0.047 lbs a.i./A) and vegetative vigor (tomato, EC_{05} = 0.001 lbs a.i./A) studies are used instead of the EC_{25} values.

The acute RQs calculated for terrestrial and endangered terrestrial plants are shown in Table 30 for plants in dry areas adjacent to the application site, and semi-aquatic areas. The acute levels of concern for terrestrial (LOC = 1) and endangered terrestrial (LOC = 1) plants are exceeded for both dry and semi-aquatic areas. The acute RQs range from 0.6 to 9.3 for terrestrial plants in dry areas and from 3.4 to 77 for terrestrial plants in semi-aquatic areas. The acute RQs for endangered terrestrial plants range from 5.0 to 48 for endangered plants in dry areas and from 29 to 306 for endangered plants in semi-aquatic areas, as shown in Table 30.

Table 30. Risk Quotients for Terrestrial and Endangered Terrestrial Plants in Dry and Semi-Aquatic Areas.

Use site/ application method	Rate (lbs a.i./A)	Acute Risk			Acute Endangered Species Risk		
		Dry Areas	Semi-aquatic Areas	Vegatative Vigor	Dry Areas	Semi-aquatic Areas	Vegatative Vigor
Rights-of-way/ ground	12	4.5	31.5	60	7.7	53.6	120
Grapes/ground	9.6	3.6	25.3	50	6.1	42.8	100
Citrus/ground	6.4	2.4	16.8	30	41	28.6	60
Alfalfa, Sugarcane, Grass seeds/ ground	3.2	1.1	8.4	15	2.0	14.3	30
Cotton/ground	1.6	0.6	4.3	10	1.0	7.1	20
Rights-of-way/ aerial	12	9.3	25.5	300	15.8	43.4	600
Alfalfa, Sugarcane/ aerial	3.2	2.5	6.8	80	4.2	11.6	160
Cotton/aerial	1.6	1.3	3.4	40	2.1	5.8	80

Risk to non-target aquatic plants

Exposure to non-target aquatic plants may occur through runoff or spray drift from adjacent treated sites. Diuron aquatic estimated environmental concentrations (EECs) were generated using the Tier I surface water model GENEEC II, a screening level model generating upper-bound EECs. Diuron EEC values were calculated based on applications to various crops using aerial or ground equipment.

The acute RQs for aquatic vascular plants are usually calculated by dividing the aquatic EECs by the EC_{50} for the duckweed *Lemna gibba*. In the case of diuron, no vascular plant toxicity study was available (one is required). Acute RQs for aquatic non-vascular plants were calculated by dividing the aquatic EECs by the acute EC_{50} (0.0024 ppm) for the green alga *Selenastrum capricornutum*.

The acute RQs for endangered aquatic vascular plants are usually calculated by dividing the aquatic EECs by the EC_{05} for the duckweed *Lemna gibba*. Since no vascular plant toxicity study was available for diuron, risk to endangered aquatic vascular plants could not be calculated. To date, there are no known non-vascular plant species on the endangered species list.

Acute RQs for aquatic non-vascular plants ranged from 9.6 (based on two aerial application to cotton) to 172 (based on one aerial application to rights-of-way) (Table 31). The acute level of concern for aquatic non-vascular plants (LOC = 0.1) plants is exceeded for all uses of diuron.

Table 31. Risk Quotients for Non-Vascular Aquatic Plants.

Use site/ application methods (number of applications)	Rate (lbs ai/A)	Single Application	Multiple Applications
		Acute only	Acute only
Rights-of-way/aerial (1)	12	172	--
Grapes/ground (1)	9.6	138	--
Citrus/ground (2)	6.4 (4.8 for 2 applications)	92	38
Fruits/ground (1)	4.0	57	--
Sugarcane/aerial (3)	3.2	48	25
Cotton/aerial (2)	1.6 (1.2 for 2 applications)	24	9.6

4. Ecological Incidents

There are 29 ecological incident reports involving diuron and non-target organisms; most of these reports are from the1990s. Of the 29 incidents, one involved birds, 16 involved fish, and 12 involved plants. One incident report included tissue analysis for both fish and plants.

Of 20 reported incidents where fish were killed, 16 resulted from direct application to ponds, which is not allowed as a legal use in the U. S. Two incidents were from use on unidentified agricultural crops where diuron subsequently ran off into adjacent waters. In one instance 12 bass and catfish were killed in Oklahoma, and in the other, 3000 unidentified fish were killed in Maryland. It is considered "probable" that diuron caused these kills, but it is unknown if the diuron was applied according to the label. Another incident resulted from spraying fence rows, with subsequent runoff into a pond, killing all of the algae within two days and 30-40 fish two days later. Diuron was applied by a pressure spray in combination with imazapyr and metsulfuron-methyl. It is likely that the spray application was the causative event, but it seems very likely that the cause of the fish deaths was low dissolved oxygen which was found to be markedly reduced; fish were observed "groping for air." The fourth incident was associated with application of a bromacil-diuron product to an electrical substation. It appears to be unlikely to have resulted from diuron because copper sulfate had been applied several days previously, and measured amounts of diuron and bromacil in the pond were very low, whereas copper concentrations were above median lethal levels for several fish species.

The absence of additional documented incidents does not necessarily mean that such incidents did not occur. Mortality incidents must be seen, reported, investigated, and submitted to the Agency in order to be recorded in the incident database. Incidents may not be noticed because the carcasses decayed, were removed by scavengers, or were in out-of-the-way or hard-to-see locations. Due to the voluntary nature of incident reporting, an incident may not be reported to appropriate authorities capable of investigating it.

5. Endangered Species

Endangered species LOCs for diuron are exceeded for terrestrial plants, herbivorous mammals and herbivorous and insectivorous birds from all uses; freshwater fish and crustaceans from all uses but cotton; and mollusks and estuarine fish from the uses on grapes and non-agricultural sites. The Agency consulted with the US Fish and Wildlife Service (FWS or the Service) on the agricultural uses of diuron in the "reinitiation" of the cluster assessments in 1988. The resulting 1989 opinion found jeopardy to the Wyoming toad (extirpated in the wild except on FWS refuges). The Service proposed a Reasonable and Prudent Alternative (RPA) (no spray zone within 100 yards of occupied habitat for ground applications and 1/4 mile for aerial application) to avoid the likelihood of jeopardizing the continued existence of this species. In addition, the Service had Reasonable and Prudent Measures (RPM) to reduce incidental take of 20 fish and two aquatic invertebrate species. The details of the RPM recommendations are provided in the FWS 1989 biological opinion.

Many additional species, especially aquatic species, have been federally listed as endangered/threatened since the biological opinion of 1989 was written; determination of potential effect to most of these species has not yet been assessed for diuron. Species- and site-specific assessments have been done for the various uses of diuron with respect to listed Pacific salmon and steelhead, in accordance with a court order, and consultation has been requested of the National Marine Fisheries Service for those that exceed criteria of concern; these latter include non-agricultural uses and the highest rates of certain agricultural uses of diuron. These assessments should not be extrapolated to other species and other parts of the U. S. In addition, endangered plants, birds, and mammals were not considered in the 1989 Biological Opinion or the consultation request for salmon and steelhead. These need to be addressed along with newly listed aquatic species and the non-crop uses of diuron for all species other than Pacific salmon and steelhead because the 1989 biological opinion dealt only with crop uses. Finally, not only are more refined methods to define ecological risks of pesticides being used, but also new data that did not exist in 1989, such as that for spray drift, are now available. The RPMs in the 1989 opinion may need to be re-assessed and consultation reinitiated, as appropriate. For additional information, please see:
http://www.epa.gov/oppfead1/endanger/effects/diuron_analysis_final2.pdf

IV. Risk Management, Reregistration and Tolerance Reassessment Decisions

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data to support reregistration of products containing the active ingredient diuron.

The Agency has completed its assessment of the occupational, residential, and ecological risks associated with the use of pesticide products containing the active ingredient diuron, as well as a diuron-specific dietary risk assessment. Based on a review of these data and on public comments on the Agency's assessments for the active ingredient diuron, EPA has sufficient information on the human health and ecological effects of diuron to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. EPA's tolerance reassessment decision was completed in July 2002, and has been included in this document. The Agency has determined that diuron products are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk reduction measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of diuron that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of diuron, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of diuron, the Agency has determined that diuron products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from use of diuron. If all changes outlined in this document are incorporated into the product labels, then all current risks for diuron will be adequately mitigated for the purposes of this determination.

B. Public Comments and Responses

When making its reregistration decision, the Agency took into account all comments received after opening of the public docket. These comments in their entirety are available in the docket (OPP-2002-0249). Comments on the risk assessment were submitted by the registrant, Griffin LLC. A formal Agency response to these comments can be found in the following document which is available in the public docket: "HED Response to Public Comments on the Diuron Preliminary Risk Assessment" dated July 9, 2003. No other comments were received on the preliminary risk assessments for diuron.

C. Regulatory Position

1. FQPA Assessment

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with this pesticide. EPA has determined that risk from dietary (food sources only) exposure to diuron is within its own "risk cup." An aggregate assessment was conducted for exposures through food, drinking water, and residential uses. The Agency has determined that the human health risks from these combined exposures are within acceptable levels. In other words, EPA has concluded that the tolerances for diuron meet the FQPA safety standards. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as the chronic and acute food exposure. The Tolerance Reassessment Decision was completed in July 2002, and can be found on the EPA website: http://www.epa.gov/oppsrrd1/REDs/diuron_tred.pdf.

Some tolerances will change because the data indicate either that a lower or higher tolerance is needed. Some will be revoked because they are no longer a regulated commodity or significant livestock feed items. Some will be deleted because a crop group tolerance will be established.

b. Determination of Safety for U.S. Population

In its July 2002, TRED, EPA determined that the established uses for diuron, with amendments and changes as specified in that document, met the safety standard under the FQPA amendments to section 408(b)(2)(D) of the FFDCA, that there is a reasonable certainty of no harm for the general population. In reaching this determination, EPA considered all available information on the toxicity, use practices, and scenarios, and the environmental behavior of diuron. As discussed in chapter 3, an acute dietary risk assessment was not performed because no adverse effects attributed to a single exposure were identified in any available study. For chronic (non-cancer) risk from food alone, the risks from diuron are not of concern. The estimated cancer dietary risk associated with the use of diuron indicates a slight exceedance above 1×10^{-6} and shows a lifetime risk estimate of 1.68×10^{-6} for the general population. However, the Agency has determined that potential dietary cancer risk is not of concern because the residues used in the calculations are from field trials conducted at the highest application rates and some residue processing data are still outstanding. Therefore, the exposure calculation is a conservative estimate.

Acute risks from drinking water exposures are not of concern. For chronic drinking water risk, drinking water monitoring data from Florida, California, and the U.S. Geological Survey National Water Quality Assessment (NAWQA) Program were used to determine the estimated environmental concentrations (EECs) in surface water. These monitoring data confirm that actual concentrations of diuron are substantially less than previous model estimates. Although modeled estimates showed only a marginal exceedance of the DWLOC, monitoring data show

concentrations substantially below the chronic DWLOC. Short-term residential exposures to diuron are not of concern. The Agency has concluded that the potential cancer risk from residential use is negligible because of the low volume of diuron used in paint and the sporadic, short-term duration of homeowner exposures.

c. Determination of Safety for Infants and Children

In its July 2002 TRED, EPA determined that the established tolerances for diuron, meet the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considered the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of diuron residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from diuron residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been removed (i.e., reduced to 1x) for diuron because: 1) there is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* or postnatal exposure; 2) a DNT study with diuron is not required; and 3) the dietary (food and drinking water) and non-dietary (residential) exposure assessments will not underestimate the potential exposures for infants and children.

d. Endocrine Disruptor Effects

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that EPA include evaluations of potential effects in wildlife. For pesticides, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the EDSP have been developed, diuron may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

The Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." Diuron is a dimethylurea herbicide. The Agency does not currently have data available to determine with certainty whether diuron has a common mechanism of toxicity with any other substances. Therefore for purposes of this Reregistration Eligibility Decision, the Agency has assumed that diuron does not have a common mechanism of toxicity with any other pesticides.

f. Tolerance Summary

A summary of EPA's July 2002 diuron tolerance reassessment is presented in Table 24. The tolerance reassessment information is presented in this RED document for the sake of completeness and for the convenience of the reader. A full description of the tolerance reassessment can be found in the Residue Chemistry Assessment for diuron dated July 9, 2003. Diuron tolerances are currently expressed as diuron *per se*. The Agency is recommending that the tolerance expression for diuron be revised to include metabolites hydrolyzable to 3,4-dichloroaniline (3,4-DCA). This determination is based on the results of the reviewed plant and animal metabolism studies. Tolerances for residues of diuron in/on plant and animal commodities are established under 40 CFR §180.106.

Table 24. Tolerance Reassessment Summary for Diuron

Commodity	Established Tolerance (ppm)[1]	Reassessed Tolerance (ppm)[2]	Comment *Correct Commodity Definition*
Tolerances Listed Under 40 CFR §180.106(a)			
Alfalfa	2	2/(TBD[3])	[*Alfalfa, forage*]
		2.0	[*Alfalfa, hay*]
Apples	1	0.10	The available data indicate that the tolerance should be reduced to 0.10 ppm. [*Apple*]
Artichokes	1	1/(TBD[3])	[*Artichoke, globe*]
Asparagus	7	7.0	Treatment of asparagus is restricted to early season, prior to the appearance of asparagus spears.
Bananas	0.1	0.05	This tolerance should be reclassified under 180.106(c), as use of diuron on banana will be restricted to HI. The available data indicate that the tolerance should be reduced to 0.05 ppm. [*Banana*]

Commodity	Established Tolerance (ppm)[1]	Reassessed Tolerance (ppm)[2]	Comment *Correct Commodity Definition*
Barley, grain	1	Reassign; 0.20	These tolerances should be reclassified under 180.106(c), as use of diuron on barley is restricted to western OR and WA. The available data indicate that the tolerance should be reduced to 0.20 ppm for barley, grain; and to 1.5 ppm for barley, straw.
Barley, hay	2	Reassign; 2	
Barley, straw	2	1.5	
Birdsfoot trefoil, forage	2	0.10	These tolerances should be reclassified under 180.106(c), as use of diuron on trefoil is restricted to western OR. The available data indicate that the tolerance should be reduced to 0.10 ppm for birdsfoot trefoil, forage and to 0.15 ppm for birdsfoot trefoil, hay.
Birdsfoot trefoil, hay	2	0.15	
Blackberries	1	Reassign; 0.10	The established tolerances for blackberries, blueberries, boysenberries, currants, dewberries, gooseberries, huckleberries, loganberries, and raspberries should be revoked concomitant with the establishment of a tolerance for: The available data indicate that these tolerances should be reduced to 0.10 ppm. [*Berry Group*].
Blueberries	1		
Boysenberries	1		
Currants	1		
Dewberries	1		
Gooseberries	1		
Huckleberries	1		
Loganberries	1		
Raspberries	1		
Cattle, fat	1	1[5]	
Cattle, meat	1	1[5]	
Cattle, meat byproducts	1	1[5]	
Citrus fruits	1	1/(TBD[3])	[*Fruit, citrus, group*]
Citrus pulp, dried	4	4/(TBD[3])	[*Citrus, dried pulp*]
Clover, forage	2	0.10	These tolerances should be reclassified under 180.106(c), as use of diuron on clover is restricted to western OR. The available data indicate that the tolerance should be reduced to 0.10 ppm for clover, forage and to 1 ppm for clover, hay.
Clover, hay	2	1	
Corn in grain or ear form (including sweet corn, field corn, popcorn)	1	0.10	Concomitant with the reassignment of this tolerance, a separate tolerance should be established for [*Corn, field, grain*]. The available data indicate that the tolerance should be reduced to 0.10 ppm.

Commodity	Established Tolerance (ppm)[1]	Reassessed Tolerance (ppm)[2]	Comment *Correct Commodity Definition*
	1	0.10	Concomitant with the reassignment of this tolerance, a separate tolerance should be established for [*Corn, pop, grain*]. The available data indicate that the tolerance should be reduced to 0.10 ppm.
	1	0.10	Concomitant with the reassignment of this tolerance, a separate tolerance should be established for [*Corn, sweet, grain*]. The available data indicate that the tolerance should be reduced to 0.10 ppm.
	1	0.10	Concomitant with the reassignment of this tolerance, a separate tolerance should be established for [*Corn, field, ear*]. The available data indicate that the tolerance should be reduced to 0.10 ppm.
	1	0.10	Concomitant with the reassignment of this tolerance, a separate tolerance should be established for [*Corn, pop ear*]. The available data indicate that the tolerance should be reduced to 0.10 ppm.
	1	0.10	Concomitant with the reassignment of this tolerance, a separate tolerance should be established for [*Corn, sweet ear*]. The available data indicate that the tolerance should be reduced to 0.10 ppm.
Corn, sweet, fodder	2	Revoke	There are no registered uses of diuron on sweet corn.
Corn, sweet, forage	2		
Corn, field fodder	2	2/(TBD[3])	This tolerance was inadvertently omitted from the 1/14/98 Final Rule technical amendment consolidating 40 CFR parts 185-186 to 40 CFR part 180. This action will reinstate this tolerance to 40 CFR part 180.106. [*Corn, field, stover*]
Corn, pop, fodder	2	2/(TBD[3])	This tolerance was inadvertently omitted from the 1/14/98 Final Rule technical amendment consolidating 40 CFR parts 185-186 to 40 CFR part 180. This action will reinstate this tolerance to 40 CFR part 180.106. [*Corn, pop, stover*]
Corn, field forage	2	2/(TBD[3])	This tolerance was inadvertently omitted from the 1/14/98 Final Rule technical amendment consolidating 40 CFR parts 185-186 to 40 CFR part 180. This action will reinstate this tolerance to 40 CFR part 180.106. [*Corn, field, forage*]

Commodity	Established Tolerance (ppm)[1]	Reassessed Tolerance (ppm)[2]	Comment ***Correct Commodity Definition***
Corn, pop, forage	2	2/(TBD[3])	This tolerance was inadvertently omitted from the 1/14/98 Final Rule technical amendment consolidating 40 CFR parts 185-186 to 40 CFR part 180. This action will reinstate this tolerance to 40 CFR part 180.106. [*Corn, pop, forage*]
Cottonseed	1	0.20	The available data indicate that the tolerance should be reduced to 0.20 ppm. [*Cotton, undelinted seed*]
Goats, fat	1	1[5]	[*Goat, fat]*
Goats, meat	1	1[5]	[*Goat, meat*]
Goats, meat byproducts	1	1[5]	[*Goat, meat byproducts*]
Grapes	1	0.05	The available data indicate that the tolerance should be reduced to 0.05 ppm. [*Grape*]
Grass crops (other than Bermuda grass)	2	2/(TBD[3])	[*Grass, forage*, *except Bermuda grass*]
Grass, hay (other than Bermuda grass hay)	2	2/(TBD[3])	[*Grass, hay, except Bermuda grass*]
Hogs, fat	1	1[5]	[*Hog, fat]*
Hogs, meat	1	1[5]	[*Hog, meat*]
Hogs, meat byproducts	1	1[5]	[*Hog, meat byproducts*]
Horses, fat	1	1[5]	[*Horse, fat]*
Horses, meat	1	1[5]	[*Horse, meat*]
Horses, meat byproducts	1	1[5]	[*Horse, meat byproducts*]
Nuts	0.1	0.1/(TBD[3])	Concomitant with the reassignment of this tolerance, separate a separate tolerance should be established for [*Filbert*].
		0.05	Concomitant with the reassignment of this tolerance, separate a separate tolerance should be established for [Nut, *macadamia*]. The available data indicate that the tolerance should be reduced to 0.05 ppm.
		0.05	Concomitant with the reassignment of this tolerance, separate a separate tolerance should be established for [*Pecan*]. The available data indicate that the tolerance should be reduced to 0.05 ppm.

Commodity	Established Tolerance (ppm)[1]	Reassessed Tolerance (ppm)[2]	Comment *Correct Commodity Definition*
		0.05	Concomitant with the reassignment of this tolerance, separate a separate tolerance should be established for *[Walnut*]. The available data indicate that the tolerance should be reduced to 0.05 ppm.
Oats, forage	2	2/(TBD[3])	These tolerances should be reclassified under 180.106(c), as use of diuron on oats is restricted to ID, OR, and WA. The available data indicate that the tolerance should be reduced to 0.10 ppm for oats, grain; and to 1.5 ppm for oats, straw.
Oats, grain	1	0.10	
Oats, hay	2	2/(TBD[3])	
Oats, straw	2	1.5	
Olives	1	1/(TBD[3])	[*Olive*]
Papayas	0.5	0.50	[*Papayas*]
Peaches	0.1	0.10	[*Peach]*
Pears	1	1/(TBD[3])	[*Pear*]
Peas	1	0.10	The available data indicate that the tolerance should be reduced to 0.10 ppm. [*Pea, field, seed*]
Peas, forage	2	2/(TBD[3])	[*Pea, field, vines]*
Peas, hay	2	2/(TBD[3])	[*Pea, field, hay*]
Peppermint, hay	2	1.5	The available data indicate that the tolerance should be reduced to 1.5 ppm. [*Peppermint, tops*]
Pineapple	1	0.10	The available data indicate that the tolerance should be reduced to 0.10 ppm.
Potatoes	1	Revoke	There are no registered uses of diuron on potatoes.
Rye, forage	2	Revoke	There are no registered uses of diuron on rye.
Rye, grain	1		
Rye, hay	2		
Rye, straw	2		
Sheep, fat	1	1[5]	
Sheep, meat	1	1[5]	
Sheep, meat byproducts	1	1[5]	
Sorghum, fodder	2	2/(TBD[3])	[*Sorghum, grain, stover*]
Sorghum, forage	2	2/(TBD[3])	[*Sorghum, grain, forage*]
Sorghum, grain	1	0.50	The available data indicate that the tolerance should be reduced to 0.50 ppm. [*Sorghum, grain, grain*]

Commodity	Established Tolerance (ppm)[1]	Reassessed Tolerance (ppm)[2]	Comment *Correct Commodity Definition*
Sugarcane	1	0.20	The available data indicate that the tolerance should be reduced to 0.20 ppm.
Vetch, forage	2	0.10	These tolerances should be reclassified under 180.106(c), as use of diuron on vetch is restricted to ID, OR, and WA. The available data indicate that these tolerances should be reduced to 0.10 ppm for vetch, forage and to 1.5 ppm for vetch, hay.
Vetch, hay	2	1.5	
Vetch, seed	1	Revoke	No longer considered a significant livestock feed item.
Wheat, forage	2	2/(TBD[3])	
Wheat, grain	1	0.50	The available data indicate that the tolerance should be reduced to 0.50 ppm.
Wheat, hay	2	2/(TBD[3])	
Wheat, straw	2	1.5	The available data indicate that the tolerance should be reduced to 1.5 ppm.
Tolerance Listed Under 40 CFR §180.106(b)			
Catfish fillets	2.0[3]	2.0	Expiration date of 06/30/05 [*Catfish*]
Tolerances To Be Proposed Under 40 CFR §180.106(a)			
Aspirated grain fractions	N/A	5.0	
Barley, bran	N/A	0.7	
Citrus, oil	N/A	TBD[3]	
Cotton, gin byproducts	N/A	TBD[3]	
Eggs	N/A	TBD[3]	
Grass, seed screenings	N/A	TBD[3]	
Grass, straw	N/A	TBD[3]	
Milk	N/A	TBD[3]	
Pineapple, process residue	N/A	0.40	
Poultry, meat byproducts	N/A	TBD[3]	
Prickly pear	N/A	0.05	

Commodity	Established Tolerance (ppm)[1]	Reassessed Tolerance (ppm)[2]	Comment *Correct Commodity Definition*
Spearmint	N/A	1.5	
Sugarcane, molasses	N/A	0.70	
Wheat, bran	N/A	0.70	

1. Expressed as diuron *per se*, unless otherwise stated.
1. To be expressed as the combined residues of diuron and its metabolites convertible to 3,4-DCA, expressed as diuron. The residues of 3,4-DCA are low but diuron residues are converted to 3,4-DCA for the tolerance expression based on the assumption that the metabolites would not be any more toxic than diuron and the consideration that the analytical methods used to collect the field trial data are not capable of measuring each metabolite individually. The reassessed tolerances are contingent upon the recommended label revisions outlined in Table B of the *Residue Chemistry Chapter For The Diuron Reregistration Eligibility Decision (RED) Document*, dated 7/29/2001.
2. TBD = To be determined. These commodities were included in the dietary risk assessment using the *Current Tolerance* level. Additional confirmatory field trial residue data are required; therefore, the final tolerance may be revised.
3. Expressed as combined residues of diuron and its metabolites convertible to 3,4-DCA.
4. Feeding study data have been submitted to reassess the established tolerances for the fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep. Residue data are not available for several potential feed items. If the maximum dietary burden does not increase when recalculated from all potential feed items after acceptable field trial data are submitted then the established tolerances for residues in fat, meat, and meat byproducts of cattle, goats, hogs, horses, and sheep can be lowered.

(1) Codex Harmonization

The Codex Alimentarius Commission has not established or proposed Codex MRLs for residues of diuron; therefore, there are no issues pertaining to harmonization of U.S. tolerances with Codex MRLs.

Canadian tolerances (from PMRA web site) include the following:

7 ppm in/on asparagus
1 ppm in/on citrus, corn, grapes, pineapple, potatoes, and wheat.

Mexican tolerances (from 1992 Diuron Residue Chemistry Registration Standard Update) are established for diuron as follows:

7 ppm in/on asparagus
4 ppm in/on dry citrus pulp
2 ppm in/on alfalfa, corn (forage), sorghum (forage), wheat (straw, forage)
1 ppm in/on artichoke, cottonseed, sugarcane, citrus fruit, apple, corn grain, peaches, potatoes, pears, pineapple, sorghum (grain), wheat (grain and straw), and grapes.
0.5 ppm in/on papaya
0.1 ppm in/on nuts

D. Risk Management and Rationale

The following is a summary of the rationale for managing risks associated with the use of diuron. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document. Application rates have been reduced and retreatment intervals have been increased for ten crops. The risk reduction by these actions have not been quantified but will reduce exposure to diuron. Table 25 lists all the crops that have revised application rates and retreatment intervals.

Table 25. Revised Crop Parameters

Crop	Current Maximum Application Rate	Current Number of Applications/ Retreatment Interval	Revised Application Rate (Annual Rate)	Number of Applications/ Other Revisions
Non-Crop Areas/ Rights-of Way	12 lb ai/A (typically 18 lb ai/A year)	Not Specified (Typically 2)	8 lb ai/A except in areas of high rainfall or dense vegetation[1] (12 lb ai/A per year)	2 applications, with a 90-day retreatment interval
Citrus (other than Flatwood area)	3.2 lb ai/A	No Limit (1.6 - 3.2 lb/A per application to max of 6.4 lb/A per year)	3.2 lb ai/A (6.4 lb ai/A per year)	2 applications, with a 60-day retreatment interval (Trees < 4 years)
				2 applications, with a 80-day retreatment interval (Trees > 4 years)
Citrus (Flatwood area)	6.4 lb ai/A (9.6 lb ai/A per year)	No Limit (1.6 - 6.4 lb/A per application to max of 9.6 lb/A per year)	6.4 lb ai/A (6.4lb ai/A per year)	2 applications, with a 60-day retreatment interval (Trees < 4 years)
				2 applications, with a 80-day retreatment interval (Trees > 4 years)
Apple	3.2 lb ai/A	1-2 (1.6 - 3.2 lb/A to max of 3.2 lb/A per year)	3.2 lb ai/A per year	1-2 applications, (1.6 - 3.2 lb/A to max of 3.2 lb ai/A per year), with a 90-day retreatment interval
Alfalfa	3.2 lb ai/A	1 application/ year	2.4 lb ai/A per year	1 application

Crop	Current Maximum Application Rate	Current Number of Applications/ Retreatment Interval	Revised Application Rate (Annual Rate)	Number of Applications/ Other Revisions
Cotton	2.2 lb ai/A	Not Specified	Preplant/Pre-emergence: (0.8 - 1.6 lb ai/A) Post-emergence: (0.8 - 1.2 lb ai/A, depending upon soil texture)	3 applications, with total ai per season limited to 0.8 lb ai/A on coarse soils, 1.5 lb ai/A on medium soils and 2.2 lb ai/A on fine soils, with a 21-day retreatment interval
Grapes	9.6 lb ai/A	2	4 lb ai/A (8 lb ai/A per year)	2 applications, with a 90-day retreatment interval
Filberts	4 lb ai/A	Not Specified (typically 2)	2.2 lb ai/A/year 1.6 lb ai/A (3.2 lb ai/A maximum)	2 applications, with a 150-day retreatment interval
Walnuts	4 lb ai/A	Not Specified (typically 2)	2.2 lb ai/A/year 1.6 lb ai/A 3.0 lb ai/A maximum in CA (3.2 lb ai/A maximum)	2 applications with a 150-day retreatment interval
Peaches	4 lb ai/A	Not Specified (typically 2)	1.6 - 2.2 lb ai/A 1.6 - 3.0 lb ai/A in CA	Do not apply within 3 months of harvest Do not apply within 8 months of harvest in the western U.S.
Grass Seed Crops	3.2 lb ai/A	1	2.4 lb ai/A	1 application, aerial applications are limited to the pacific northwestern U.S.

1 High rainfall is defined as >40 inches per year; high density vegetation is defined as >90% weed ground cover.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

Diuron is not acutely toxic. No adverse effects attributed to a single exposure were identified in any available study. Therefore, no acute dietary risk assessment was conducted and no mitigation is needed.

The chronic non-cancer dietary analysis indicates all risk estimates are below the Agency's level of concern for all population subgroups for diuron. The highest chronic dietary risk estimates are 7% of the chronic PAD, for diuron, with the highest exposed population subgroup being children (1-6 years). Therefore, the chronic dietary (food) risk estimate is not of concern, and no risk reduction measures are necessary.

In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment, the Cancer Assessment Review Committee has classified diuron as "known/likely to be carcinogenic to humans." The lifetime dietary cancer risk estimate is 1.68×10^{-6} for diuron, representing a borderline exceedance. Generally, the Agency is concerned when cancer risk estimates exceed the range of 1×10^{-6} or one in one million, although this negligible risk standard should not be viewed as a bright-line standard. As discussed previously, the residues used in the calculations are from field trials conducted at the highest application rates and from tolerance level residues from certain commodities. In addition, some processing data are still outstanding, which would enable further refinement to the risk assessment. Therefore, the exposure calculation is a conservative estimate and the Agency is not concerned with the dietary cancer risk from diuron use.

b. Drinking Water Risk Mitigation

In the preliminary risk assessment for diuron, surface and groundwater concentrations were modeled based on application to citrus in Florida; the crop with the highest application rate. An application rate of 6.4 lbs ai/acre could be applied, with a second application of diuron applied at a rate of 3.2 lbs ai/acre applied later for the seasonal maximum application of 9.6 lbs ai/acre. Based on information gathered after the initial risk assessment was prepared, the Agency has analyzed surface water monitoring data from Florida and California that has enabled us to conduct a more refined drinking water assessment. In addition, the registrant has agreed to reduce the application rate and increase the retreatment interval for citrus. The application rate on Florida citrus (Flatwood area) is reduced to 6.4 lbs ai/acre per year, with a 60-day retreatment interval for trees less than 4 years old and an 80-day retreatment interval for trees older than 4 years. Application rate reductions in other crops (Table 25) will also serve to reduce drinking water exposure to diuron in drinking water.

c. Residential Risk Mitigation

Residential exposure to diuron can occur when homeowners apply diuron-treated paints or stains or apply diuron to ornamental ponds or aquariums. For residential paint and stain uses, the short-term inhalation risk from exposure to the liquid formulation of diuron indicates that inhalation MOEs are more than the target of 100 with baseline level of clothing. Therefore, the short-term risks to homeowners from paint and stain use is not of concern. Diuron application to ponds and aquariums is not of concern and does not require further mitigation. In addition, the registrant has agreed to eliminate diuron application to home lawns.

(1) Residential Handler Mitigation

The lifetime cancer risk estimates for applying diuron-treated paint and stain products once per year for 50 years range from $9.5x10^{-7}$ to $1.1x10^{-6}$. However, the Agency believes these exposures are not of concern because it is unlikely that a homeowner would apply diuron treated paint or stain every year for 50 years. In addition, approximately one percent of all paint contains diuron and that paint contains a maximum of 0.0532 lbs. of diuron per gallon. Therefore, the Agency believes the risks to homeowners from applying diuron-treated paints and stains are negligible and not of concern. No further risk mitigation is necessary.

(2) Residential Postapplication Risk Mitigation

Post-application exposure to diuron-treated paints, and stains is anticipated to be only by the inhalation route, as the treated materials will have dried and be relatively inert. The results of Multi-Chamber Concentration and Exposure Model, as discussed previously, coupled with diuron's low vapor pressure (2×10^{-7} mm Hg at 30 °C), show negligible postapplication inhalation exposure. Furthermore, diuron-treated paint is only likely to be used in rooms where high humidity is expected, such as a bathroom, and would rarely be used in the entire house. It is unlikely that a homeowner would receive a significant amount of postapplication inhalation exposure from diuron-treated paint, as the very nature of its use is as a mildewcide, and any substantial loss of the active ingredient from the paint would render the product ineffective. No risk mitigation is necessary for postapplication exposure to homeowners.

d. Aggregate Risk Mitigation

(1) Acute Aggregate Risk

There are no adverse effects expected from a single exposure to diuron; therefore, an acute aggregate risk assessment was not conducted.

(2) Short-term Aggregate Risk

Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water. Short-term aggregate risks from food, residential inhalation, and drinking water are not of concern; therefore, no mitigation is required.

(3) Chronic (Non-Cancer) Aggregate Risk

The chronic (non-cancer) aggregate risk assessment addresses exposure to diuron residues in food and water; there are no diuron uses that could result in chronic residential exposure. The estimated environmental concentration (EEC) for surface water (<1 ppb) does not exceed the drinking water level of comparison (DWLOC) of 28 ppb for the most sensitive population subgroup (children 1-6). Chronic dietary (food + water) risks are below EPA's level of concern. Chronic aggregate risk is also below EPA's level of concern; therefore, no mitigation is required.

(4) Chronic (Cancer) Aggregate Risk

As mentioned previously, dietary risk from food is estimated to slightly exceed 1 x 10^{-6}, based on field trial data and assuming maximum application rates. This estimate can be refined with additional residue data. Based on monitoring data, drinking water cancer risk is estimated in the 1 x 10^{-6} range. Lifetime exposure from residential uses is negligible. Although the combined risk slightly exceeds 1 x 10^{-6}, EPA believes that, given the weight of evidence, diuron cancer risk is not of concern. The Agency does not apply the negligible risk standard for cancer (1 x 10^{-6} or one in a million) as a bright line test because of the lack of precision in the quantitative cancer risk assessment. There are protective assumptions in both the toxicological data used to derive the cancer potency of a substance and in the exposure calculations. In addition, other risk mitigation measures discussed in this document will result in lower aggregate risks.

e. Occupational Risk Mitigation

The Agency met with the registrant to discuss occupational risk mitigation on August 6, 2003 and September 10, 2003. Stakeholders submitted information regarding use rates, acreage, and use practices to the Agency in order to further refine the cancer risk assessment. This information was confirmed and used by the Agency to further characterize the occupational risks.

(1) Handler Risk Mitigation

Handler exposure assessments are completed by EPA using a baseline exposure scenario and, if required, increasing levels of mitigation (PPE and engineering controls) to achieve an adequate margin of exposure (MOE). For diuron the target MOE for workers is 100. Analyses for handler/applicator exposures were performed using PHED, ORETF, and available studies. The non-cancer calculations indicate that the MOEs for many handler scenarios including all agricultural applicator scenarios are above 100 at the baseline level and are not of concern. Generally for diuron, the worker risk mitigation is driven by the cancer assessment.

For occupational cancer risks between 1x10^{-6} and 1x10^{-4}, EPA carefully evaluates exposure scenarios to seek cost effective ways to reduce cancer risks to the greatest extent feasible, preferably to a risk of 1x10^{-6} or less. For the scenarios listed below, EPA has determined that the use of PPE or engineering controls would further reduce exposure to handlers but for some scenarios, such as mixing/loading and applying with a backpack sprayer, and applying with a rights-of-way sprayer, engineering controls are not available. For other scenarios, such as applying granular formulations with a tractor-drawn spreader, some engineering controls may be available but they are not universally used for this type of application. The Agency encourages the use of engineering controls in all settings where practical and feasible, and allows for handlers to reduce PPE when engineering controls are used. However, EPA concludes that the risk reduction potential of requiring engineering controls for additional scenarios would not be commensurate with the costs and difficulties associated with implementing the requirement.

To address cancer risks to occupational handlers, the registrant has agreed to the following mitigation measures, which are necessary, reasonable, and cost-effective:

- Eliminate aerial applications except for rights-of-way, alfalfa, cotton, winter barley, winter wheat, sugarcane, and grass seed crops (in the pacific northwestern U.S. only).

- All wettable powder products will be voluntarily canceled.

- Use of the pump-feed backpack spreader and the gravity-feed backpack spreader will be prohibited.

- Cancel use of diuron on home lawns.

- Application of diuron using a spoon will be prohibited.

EPA has determined that worker risks from exposure to diuron in the scenario listed below would be adequately mitigated through the use of the following PPE: long pants, long-sleeved shirt, socks, shoes, and gloves.

- Applying Granular Formulations by Hand;
- Loading/Applying Granular Formulations with a Belly Grinder; and
- Loading/Applying Granular Formulations with a Push-Type Spreader.

EPA has determined that worker risks from exposure to diuron in the scenarios listed below would be adequately mitigated through the use of the following PPE: long pants, long-sleeved shirt, dust mist respirator, socks, shoes, and gloves:

- Loading Granular Formulation for Tractor-Drawn Spreader Application;
- Applying Granular Formulations with a Tractor-Drawn Spreader;
- Applying Sprays Using a Rights-of-Way Sprayer (no PPE required in closed cab);
- Applying Sprays Using a High-Pressure Handwand;
- Mixing/Loading/Applying Liquids Using a Low Pressure Handwand; and
- Mixing/Loading/Applying Liquids Using a Backpack Sprayer.

EPA has determined that worker risks from exposure to diuron in the scenarios listed below would be adequately mitigated through the use of the following PPE: long pants, long-sleeved shirt, dust mist respirator, socks, shoes, gloves, and apron:

- Mixing/Loading Liquids for Aerial Application;
- Mixing/Loading Liquids for Chemigation Application;
- Mixing/Loading Liquids for Groundboom Application;
- Mixing/Loading Liquids for Rights-of-Way Application;
- Mixing/Loading Liquids for High-Pressure Handwand Application;
- Mixing/Loading Dry Flowable for Aerial Application;

- Mixing/Loading Dry Flowable for Chemigation Application
- Mixing/Loading Dry Flowable for Groundboom Application;
- Mixing/Loading Dry Flowable for Rights-of-Way Application; and
- Mixing/Loading Dry Flowable for High-Pressure Handwand Application.

EPA has determined that worker risks from exposure to diuron in the scenario listed below would be adequately mitigated through the use of an enclosed cockpit or enclosed cab.

- Applying Sprays Aerially; and
- Flagging for Spray Applications.

- Applying sprays with rights-of-way sprayers for commercial applicators (scenario 7), the assessment is based on the worker applying 1000 gallons of liquid with a rights-of-way sprayer. The Agency has received information indicating that workers typically use 4.8 - 6.4 lbs ai/A. Higher application rates are used on less than 10 percent of the acreage and are limited to difficult to treat areas where longer residual control is necessary. In addition, the Agency has concluded that the estimate of applying 1000 gallons of product per day with 30 days of exposure per year to be a high estimate that would not reflect actual exposure to workers. Typically, the truck where the applicator rides has the controls for operating the sprayer inside the cab. With the windows closed, the driver of the truck would not be required to wear any PPE. However, an applicator outside the truck operating the spray equipment, would be required to wear maximum PPE. EPA has concluded that with the addition of maximum PPE, this scenario would not require additional risk mitigation.

- Applying sprays for high pressure handwand application for commercial applicators (scenario 8), the assessment is based on the worker applying 1000 gallons of liquid with a high pressure handwand. The Agency has received information about high pressure handwand use. The information indicates that most non-crop applications would be made by a truck-mounted boom. The high pressure handwand would be used only around fence or sign posts or other areas that are not accessible with the truck-mounted boom. It is estimated that the high pressure handwand is used in less than 10 percent of rights-of-way treatment. Therefore, the Agency has determined that the estimate of applying 1000 gallons of product per day with 30 days of exposure per year to be a high estimate that would not reflect actual exposure to workers and would not require additional risk mitigation beyond maximum PPE.

- Loading/applying granulars for belly grinder applications for commercial applicators (scenario 18), the application rate used in the assessment is 87.1 lbs ai/A, much higher than any product labels currently on the market. The highest application rate on a marketed label is 12 lbs ai/A. The registrant has agreed to limit the application rates for non-crop uses to 12 lbs ai/A. In addition, the

registrant has agreed to limit the percent active ingredient in all granular products to no more than 8 %. The Agency has received information about belly grinder use; this information indicates that most non-crop applications would be applied by a truck-mounted boom. The belly grinder would mostly be used around fence or sign posts or other areas that are not accessible with the truck-mounted boom. In this type of treatment, the applicator typically applies 7.2 lb ai/A. In a typical day an applicator would apply diuron on eight to twelve small sites equaling approximately two acres. Therefore, the Agency has concluded that the estimate of applying diuron at the high application rate to be a high estimate that would not reflect actual exposure to workers. No additional risk mitigation is required beyond maximum PPE.

(2) Post-application Risk Mitigation

The Restricted Entry Interval (REI) represents the amount of time required for residues to dissipate in treated areas prior to beginning a job or task in that area such that the resulting exposures do not exceed the Agency's level of risk concern. In order to determine the REI for a crop, EPA calculates the number of days that must elapse after pesticide application until residues dissipate and risk to a worker falls below the target risk level. For a specific crop/pesticide combination, the duration required to achieve the target risk estimate can vary depending on the activity assessed.

Only the crops whose foliage can be sprayed without damage were assessed for postapplication exposure. The crops that can be sprayed without foliage damage are oats, wheat, birdsfoot trefoil, clover, grass grown for seed, alfalfa, asparagus, pineapple and sugarcane.

In general, the Agency is concerned when postapplication occupational cancer risk estimates exceed 1 $x10^{-4}$. Postapplication cancer risks for commercial and private farm workers were calculated at the typical application rate only for each crop that received foliar applications. All cancer risks to commercial and private farm workers were less than 1 x 10^{-4} on the day of treatment and not of concern. Therefore, no additional risk mitigation is necessary, the REI for diuron labels will remain at 12-hours with the following early entry PPE required: coveralls over long sleeved shirt and long pants, waterproof gloves, chemical resistant footwear plus socks, protective eye wear and chemical resistant headgear for overhead exposures.

2. Environmental Risk Mitigation

EPA's ecological risk assessment shows minimal exceedance of the levels of concern for acute risk to birds. Chronic risk to birds could not be calculated due to a lack of chronic avian toxicity data; these data are required. Chronic RQs for very small mammals (15 grams) range from 0.1 to 9.2; all other mammalian RQs are below levels of concern. Acute RQs for freshwater fish and invertebrates are relatively low ranging from 0.03 to 2.6; however, limited incident data suggest that diuron may pose an acute risk to fish. Chronic RQs for freshwater fish range from 0.3 to 9. Acute and chronic risk quotients for estuarine and marine fish and invertebrates are low, with the highest RQ of 1.3 for chronic risk to marine invertebrates, based on the 12 lb. application rate

to rights-of-way. Of greatest concern is the potential acute risk to non-target plants, with RQs for terrestrial plants ranging from 1 to 77 and RQs for endangered terrestrial plants ranging from 5 to over 300. Acute RQs for aquatic non-vascular plants range from 10 to 172. RQs for aquatic vascular and endangered aquatic vascular plants could not be calculated because no toxicity data were available; these data are required. Acute risk to non-target plants is further supported by available incident data.

Many of the mitigation measure mentioned earlier in this section will also serve to decrease risk to non-target species. These include:

- Eliminate aerial applications except for rights-of-way, alfalfa, cotton, winter barley, winter wheat, sugarcane, and grass seed crops (in the pacific northwestern U.S. only).

- Reducing applications rates and increasing interval between applications for numerous crops as shown in Table 25;

- Implementing labeling with best management practices to reduce spray drift; and

- Reducing application rates on walnuts, filbert, and peaches to address risk to endangered salmon and steelhead in California and the Pacific northwest.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information must also be placed on the labeling of all end-use products containing diuron. For the specific labeling statements, refer to Section V of this document.

a. Endangered Species Statement

The Agency has developed the Endangered Species Protection Program to identify pesticides whose use may cause adverse impacts on endangered and threatened species, and to implement mitigation measures that address these impacts. EPA is not requiring specific label language at the present time relative to threatened and endangered species. The general risk mitigation required through this RED will serve to protect listed species of potential concern until such time as the agency refines its risk assessment for birds, mammals, aquatic species and plants from the uses of diuron. If in the future, specific measures are necessary for the protection of listed species, the Agency will implement them through the Endangered Species Protection Program.

The Endangered Species Protection Program as described in a Federal Register notice (54 FR 27984-28008, July 3, 1989) is currently being implemented on an interim basis. As part of the interim program, the Agency has developed County Specific Pamphlets that articulate many of the specific measures outlined in the Biological Opinions issued to date. The Pamphlets are available for voluntary use by pesticide applicators on EPA's website at www.epa.gov/espp. A final Endangered Species Protection Program, which may be altered from the interim program, was proposed for public comment in the Federal Register December 2, 2002.

b. Spray Drift Management

The Agency has been working closely with stakeholders to develop improved approaches for mitigating risks to human health and the environment from pesticide spray and dust drift. As part of the reregistration process, we will continue to work with all interested parties on this important issue.

From its assessment of diuron, as summarized in this document, the Agency concludes that certain measures are needed to address the potential for off-target drift from use of diuron products. Label statements implementing these measures are listed in the "spray drift management" section of the label table, which will be issued separately. In the future, diuron product labels may need to be revised to include additional or different drift label statements.

The following label language is required to address the risks from off-target drift for diuron products.

For non-WPS products:

"Do not apply this product in a way that will contact workers or other persons either directly or through drift."

For all diuron products applied as a liquid (including non-WPS products):

"Requirements for reducing spray drift for diuron ground and aerial applications"

"Use best practices to avoid drift to all other crops and non-target areas. Do not apply when conditions favor drift from target areas. The interaction of many equipment- and weather-related factors determine the potential for spray drift. Avoiding spray drift at the application site is the responsibility of the applicator. The applicator must follow the most restrictive precautions to avoid drift, including those found in this labeling as well as applicable state and local regulations and ordinances."

"Do not make aerial or ground applications when the wind speed exceeds 10 miles per hour."

"Do not make aerial or ground applications into temperature inversions."

"Apply as a medium or coarser spray (according to ASAE standard 572) for standard nozzles."

Additional requirements for ground applications:

"When applying to crops, apply with nozzle height no more than 6 feet above the ground or crop canopy. When applying to non-crop areas, use lowest nozzle height consistent with safety and efficacy. Direct spray into target vegetation."

Additional requirements for aerial applications:

"The boom length must not exceed 75% of the wingspan or 90% of rotor blade diameter."

"When aerial applications are made with cross-wind, the swath will be displaced downwind. The applicator must compensate for this displacement at the downwind edge of the application area by adjusting the path of the aircraft upwind."

"When applying to crops, do not release spray at a height greater than 6 to 10 feet above the ground or crop canopy. When applying to non-crop areas, apply at a minimum safe altitude above the area being treated."

"Release spray at the lowest height consistent with efficacy and flight safety."

"Do not apply by air if drift can occur to sensitive non-target crops or plants that are within 100 feet of the application site."

V. What Registrants Need to Do

The Agency has determined that diuron is eligible for reregistration provide that: (i) additional data that the Agency intends to require confirm this interim decision; and (ii) the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Summary Table in Section D below. The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

A. <u>For diuron technical grade active ingredient products</u>, the registrant needs to submit the following items.

Within 90 days from receipt of the generic data call-in (DCI):

(1) completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and
(2) submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

(1) cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Diane Isbell at (703) 308-8154 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Diane Isbell
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Diane Isbell
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

B. For products containing the active ingredient diuron, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

(1) completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and
(2) submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

(1) two copies of the confidential statement of formula (EPA Form 8570-4);

(2) a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";
(3) five copies of the draft label incorporating all label amendments outlined in Table 39 of this document;
(4) a completed for certifying compliance with data compensation requirements (EPA Form 8570-34);
(5) if applicable, a completed for certifying compliance with cost share offer requirements (EPA Form 8570-32); and
(6) the product-specific data responding to the PDCI.

Please contact Barbara Briscoe at (703) 308-8178 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Barbara Briscoe
US EPA (7508C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Barbara Briscoe
Office of Pesticide Programs (7508C)
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic data base supporting the reregistration of diuron for the above eligible uses has been reviewed and determined to be substantially complete. However, the following data requirements are necessary to confirm the reregistration eligibility decision documented in this RED.

Toxicology Data:

- 28-day inhalation study

Product and Residue Chemistry Data:

- New confidential statements of formula reflecting preliminary analyses of current products together with discussions of formation of impurities
- UV/Visible absorption data/spectra
- Independent lab validation for analytical method
- Multiresidue methods for diuron and metabolites in plants and livestock
- Magnitude of residue field trial data for: globe artichoke; barley hay; cotton gin byproducts; field corn aspirated grain fractions, forage and stover; sweet corn, stover; sweet corn, forage; filbert; grass forage, hay, seed screenings, and straw; pear; oat forage, hay; olive; field pea vines and hay; sorghum aspirated grain, fractions, stover, and forage; and wheat forage and hay.
- Processing data for field corn and olives
- Metabolism study in fish

Occupational Exposure Data:

- Exposure study of mixing/loading/applying dry flowable with low-pressure handwand
- Worker exposure resulting from contact with treated soil and soil dissipation study
- Exposure study for mechanical harvesting alfalfa and asparagus

Environmental Fate and Ecological Effects Data:

- Avian reproduction study - diuron
- Freshwater aquatic invertebrate life-cycle toxicity study - diuron
- Estuarine/marine fish early life-cycle toxicity study - diuron
- Nontarget aquatic plant toxicity study - diuron
- Upgrade of leaching-adsorption-desorption study - diuron
- Hydrolysis of MCPDMU
- Aerobic Soil Metabolism of MCPDMU
- Aerobic Aquatic Metabolism of MCPDMU
- Anaerobic Aquatic Metabolism of MCPCMU
- Leaching-Adsorption-Desorption of MCPDMU

2. Labeling for Manufacturing-Use Products

To ensure compliance with FIFRA, manufacturing use product (MUP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MUP labeling should bear the labeling contained in the labeling table, which will be issued separately.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements, accompanies this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 26.

C. Existing Stocks

Registrants may generally distribute and sell products bearing old labels/labeling for 12 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 24 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-

case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; *Federal Register*, Volume 56, No. 123, June 26, 1991.